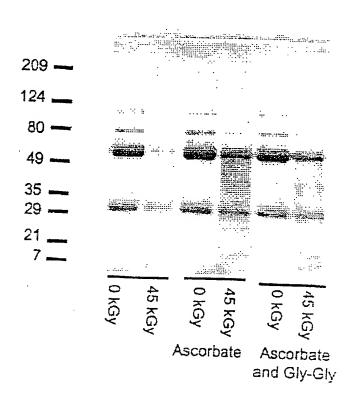


#### Gamma Irradiation of Liquid IGIV in the Absence or Presence of Ascorbate Alone or in Addition to Gly-Gly

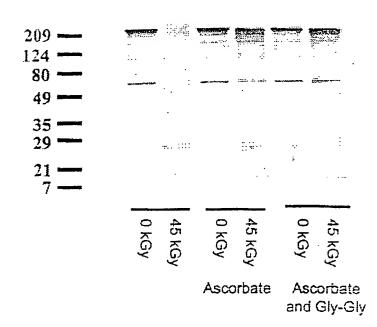
Liquid IGIV, Reduced 5-15%





#### Gamma Irradiation of Liquid IGIV in the Absence or Presence of Ascorbate Alone or in Addition to Gly-Gly

Liquid IGIV, Non-Reduced 5-15%





### Intion of a Glycosidase In the Presence of Ascorbate and Gly-Gly

Nonreduced

2

5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy

> 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy

1.7 kGy/hr, 45 kGy 0 kGy

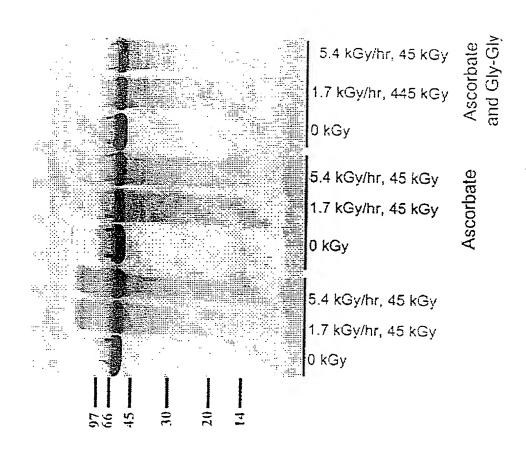
and Gly-Gly Ascorbate

Ascorbate

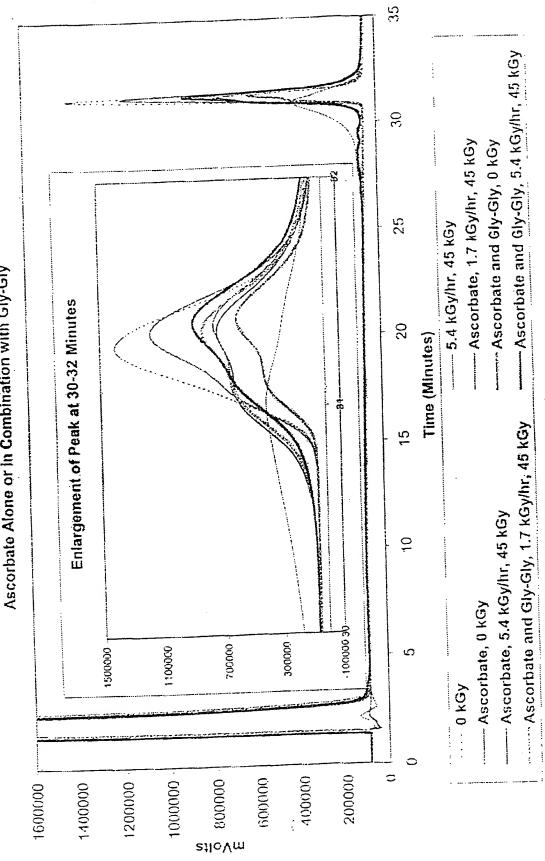
Ascorbate Ascorbate

### rorror esected Gamma Irradiation of a Sulfatase In the Presence of Ascorbate and Gly-Gly

Reduced

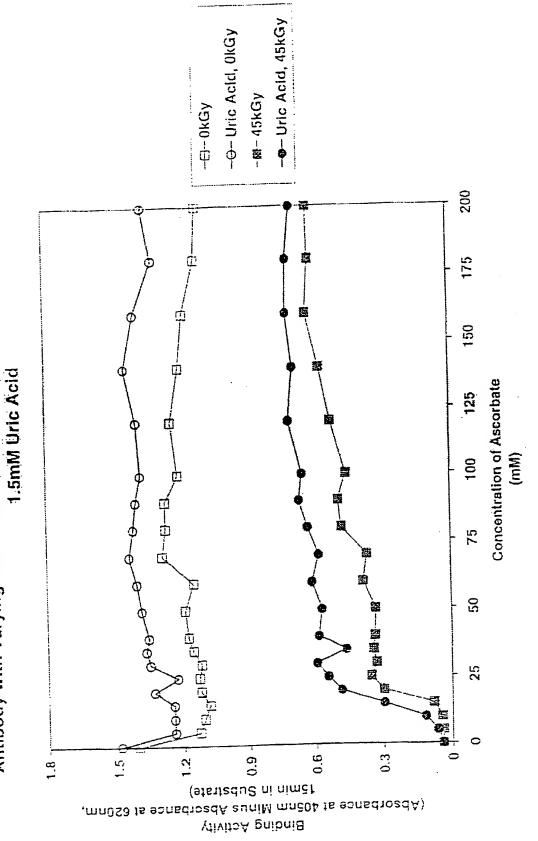


Gamma Irradiation of a Galactosidase in the Piesence or Absence of Ascorbate Alone or in Combination with Gly-Gly



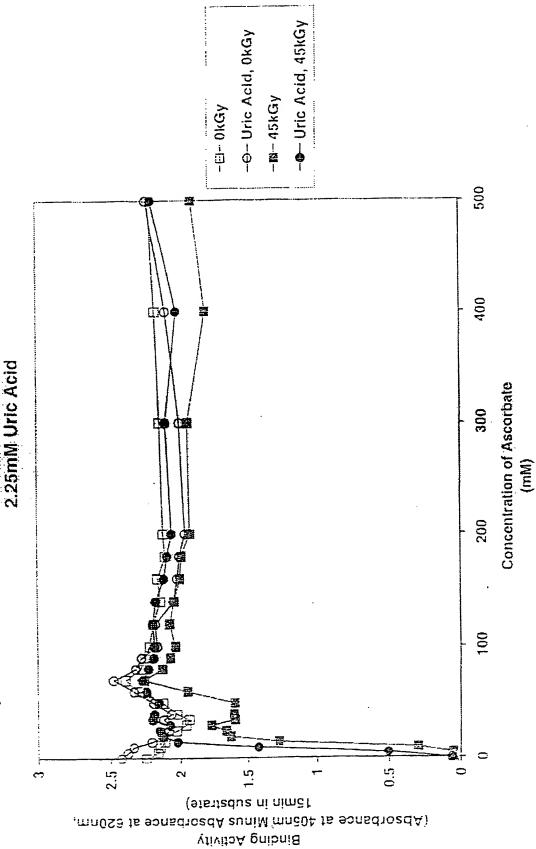


Antibody with Varying Ascorbate Concentrations in the Presence or Absence of Gamma Irradiation of Immobilized Anti-Insulin Monoclonal





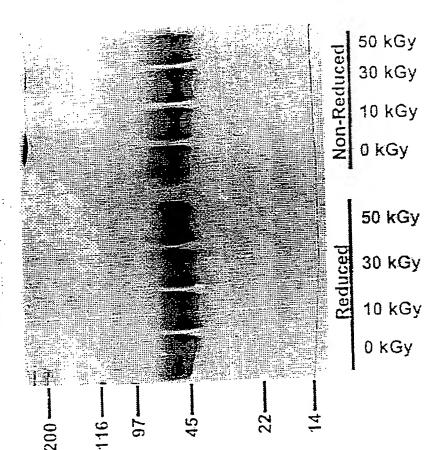
Antibody with Varying Ascorbate Concentrations in the Presence or Absence of Gamma Irradiation of Immobilized Anti-Insulin Monoclonal

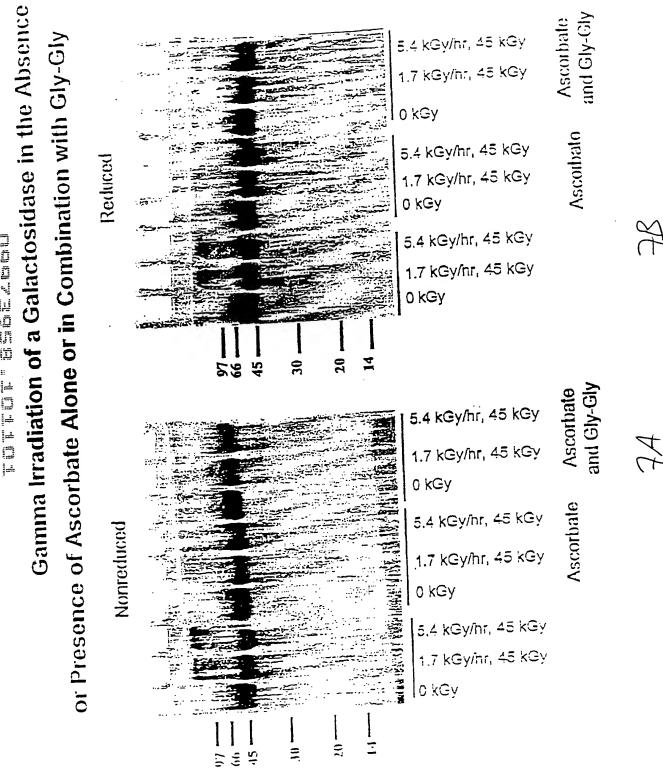


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### Gamma Irradiation of a Lyophilized Galactosidase In the Presence of 200mM Ascorbate and 200mM Gly-Gly

Reduced & Non-Reduced, 10%





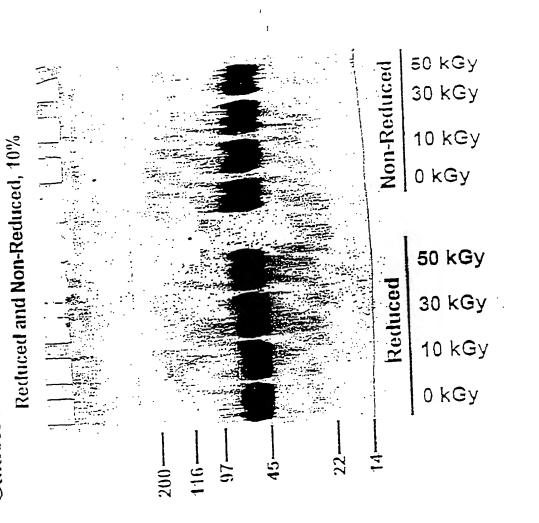
35 -Ascorbate and Gly-Gly, 5.4 kGy/hr, 45 kGy 30 Gamma irradiation of a Galactosidase in the Presence or Absence of - Ascorbate, 1.7 kGy/hr, 45 kGy -Ascorbate and Gly-Gly, 0 kGy -- 5.4 kGylhr, 45 kGy 25 Ascorbate Alone or in Combination with Gly-Gly Enlargement of Peak at 30-32 Minutes 20 Time (Minutes) - Ascorbate and Gly-Gly, 1.7 kGyfir, 45 kGy 15 Ascorbate, 5.4 kGyllir, 45 kGy 10 ---- Ascorbate, 0 kGy -1000003A 300000 7000007 1500000 1100000  $\cdots \sim 0 \; \text{kGy}$ C C 200000 #Ic√n BUOXX 600000 4000XX 140XX100 10XXX00 1200000 16000XX

 $\mathcal{X}$ 

Gamma Irradiation of a Lyophilized Galactosidase in the Absence and Presence of 100mM Ascorbate

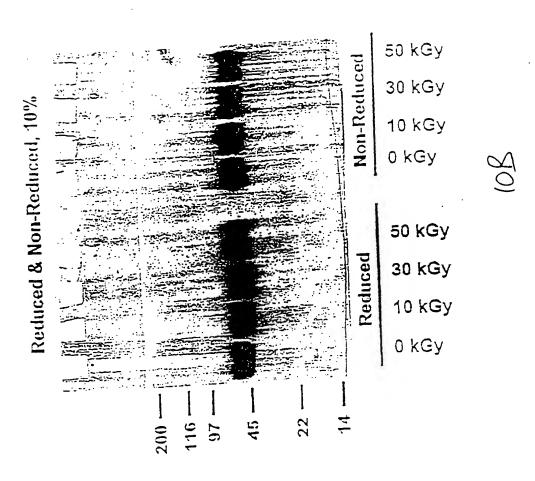
	45 kGy 0 kGy	.With Ascorbate	a
	45 kGy 0 kGy	Without Ascorbate	
209- 124- 80- 49- 35- 21- 7-		•	

Galactosidase In the Absence of Stabilizers

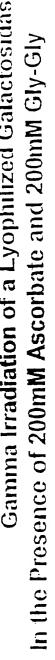


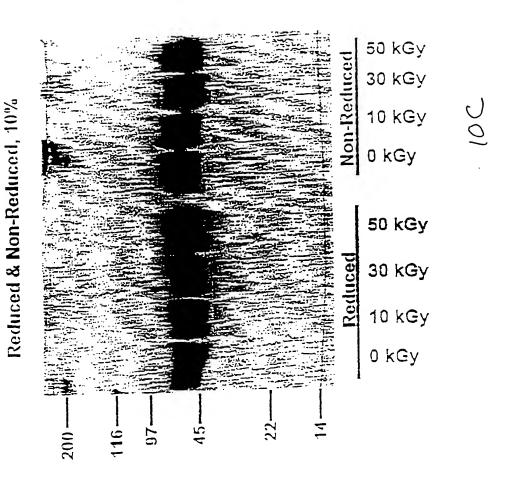
10A

Gamma Irradiation of a Lyophilized Galactosidase In the Presence of 200mM Ascorbate



Gamma Irradiation of a Lyophilized Galactosidase





M 45kGy M OkGy **Urokinase in PBS Urokinase in PPG400** Dried Urokinase mn0S8 ts eonscroedA suniM mn204 ts eonscroedA

O O O O

S O O

S O O

of Dried Urokinase Suspended in PPG400

Gamma Irradiation

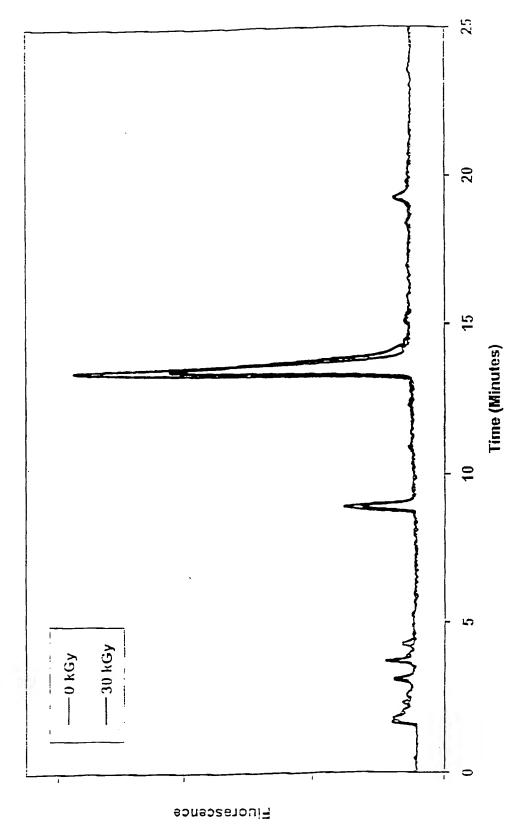
nggyzggg..............

M 45kGy ■ OkGy Immobilized Monoclonal Antibody in the Presence of various PPG2000 **Samma** Irradiation of **PPG1200 PPGs** PPG400 PBS 

120 -m-Lyophilized Control, --- Insoluble Samples, 100 Gamma Irradiation of Trypsin In the Presence of 45 kGy 45 kGy Increasing Amounts of Added Moisture 80 Percent Water (In PPG 400) 09 40 20 20 100 10 20 30 0 23 70 09 ဥ္သ 90 (Activity of Irradiated Sample / Activity of Unirradiated Sample) Percent Protection

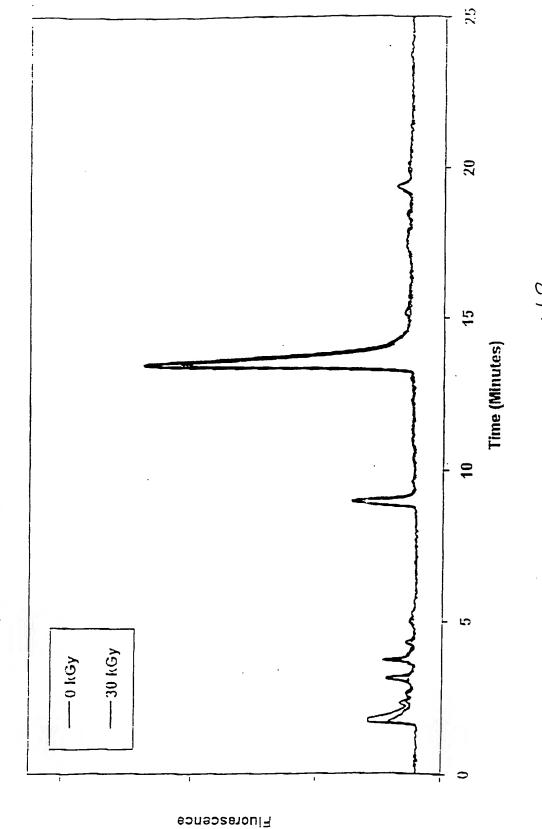
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Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400

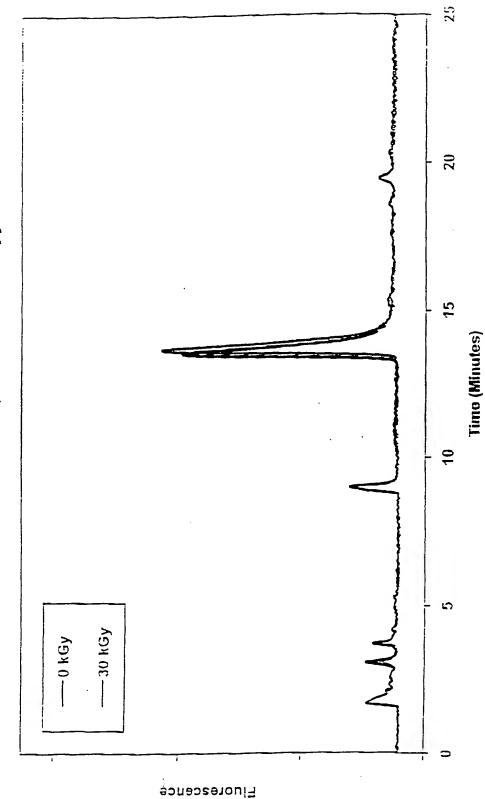


(4) (4)

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400 and 125 mM Trolox C



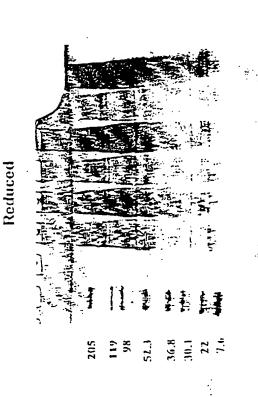
Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400 and a Stabilizer Mixture of 62.5mM TroloxC, 100mM Lipoic Acld, 100mM Coumaric Acid, and 100mM n-Propyl Gallate



HC HC

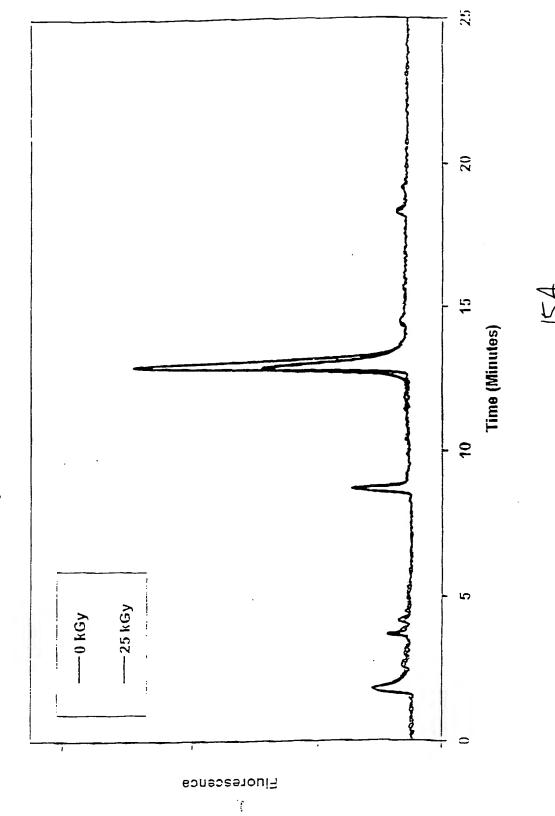
# Gamma Irradiation of Porcine Heart

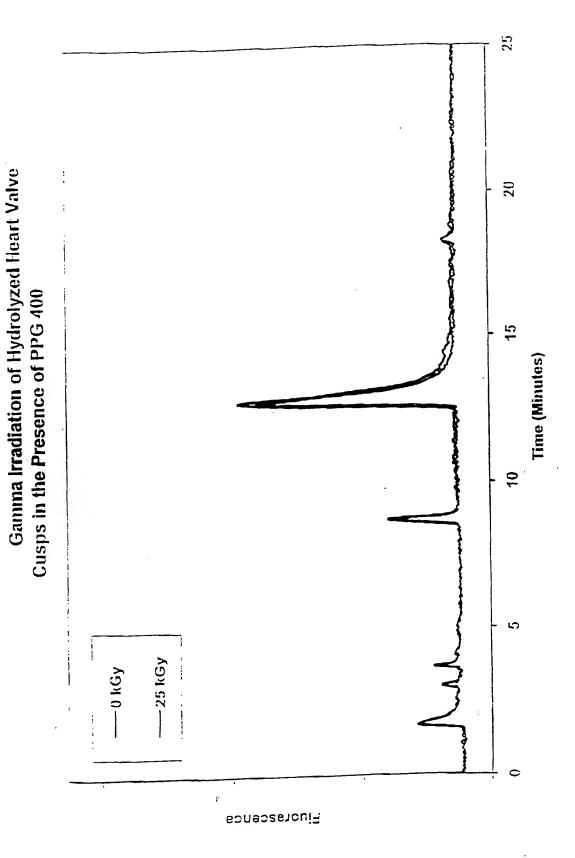
Valve Cusps in the Presence of PPG400 with Various Stabilizers



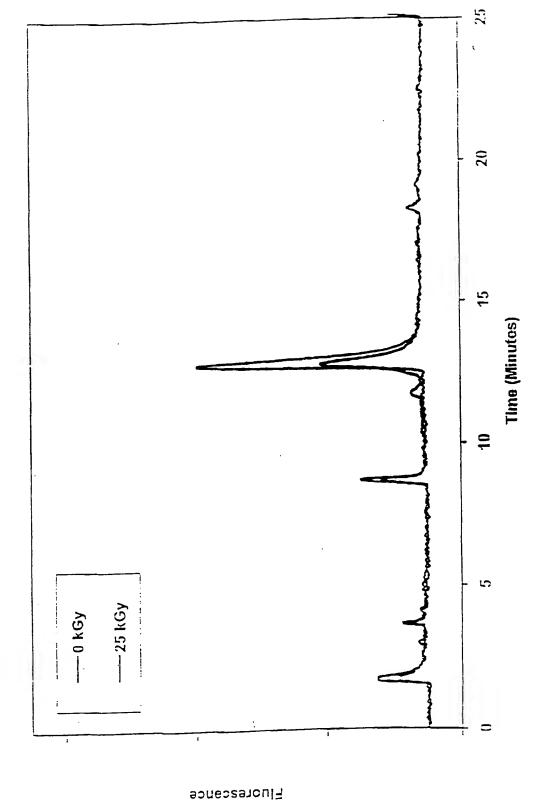
- 1. Molecular Weight Markers
- 2. Blank
- 3. PPG400, 0 kGy
- 4. PPG400, 30 kGy
- 5. PPG400 and TroloxC, 0 kGy
- 6. PPG400 and TroloxC, 30 kGy
- 7. PPG400 and a Cocktail of TroloxC, Lipoic Acid, Coumaric Acid, and n-Propyl Gallate, 0 kGy
- Coumaric Acid, and n-Propyl Gallate, 30kGy 8. PPG400 and a Cocktail of TroloxC, Lipoic Acid,

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS

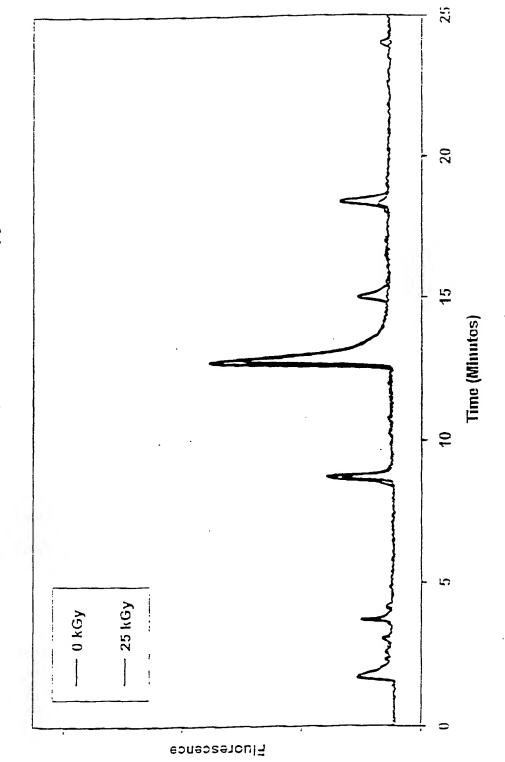




Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO



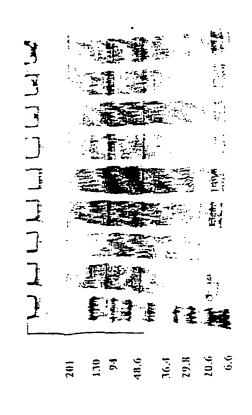
Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO and a Stabilizer Mixture of 167 mM Ascorbate, 166 mM Coumaric Acid, and 100 mM n-Propyl Gallate



# Gamma Irradiation of Porcine Heart







#### 1. Molecular Weight Markers

- 2. PBS, 0 kGy
- 3. PBS, 25 kGy
- 4. PPG400, 0 kGy
- 5. PPG400, 25 kGy
- 6, 50% DMSO, 0 kGy
- 7. 50% DMSO, 25 kGy
- Commaric Acid, and n-Propyl Gallate, 0 kGy 8, 50% DMSO and Cocktall of Ascorbate,

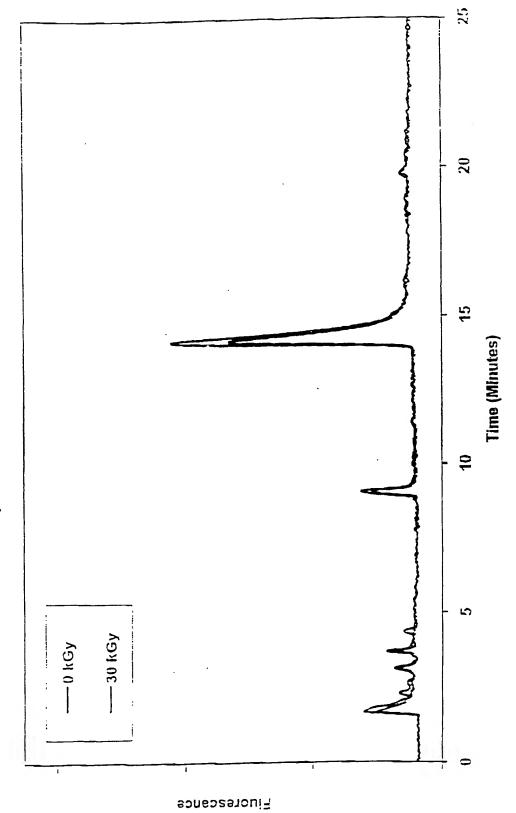
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2 9

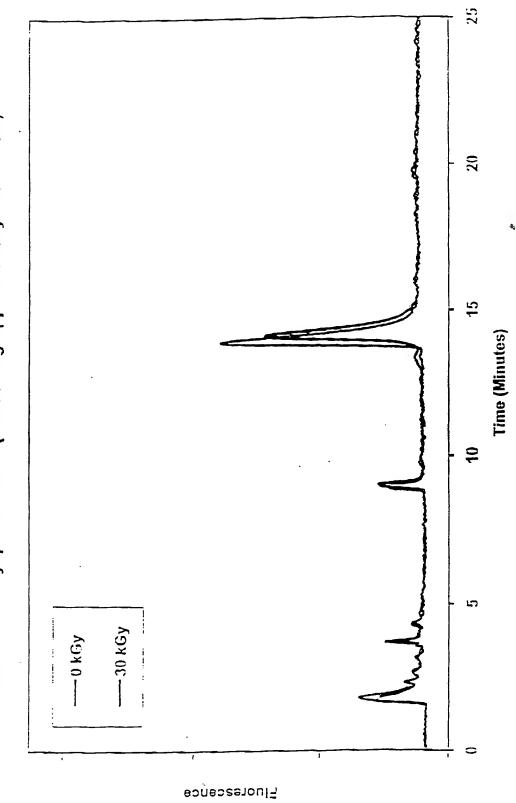
5

Coumaric Acid, and n-Propyl Gallate, 25 kGy 9. 50% DMSO and Cocktall of Ascorbate,

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS

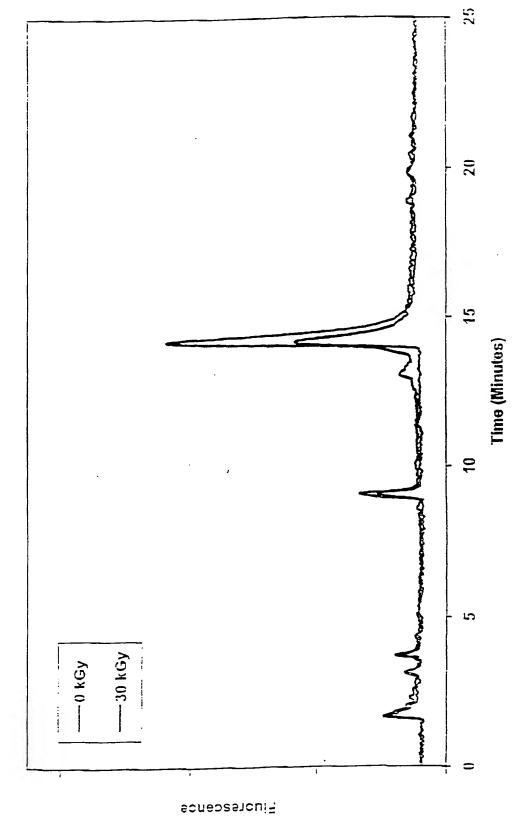


Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of a Cryopreservative (Containing Approximately 20% DMSO)



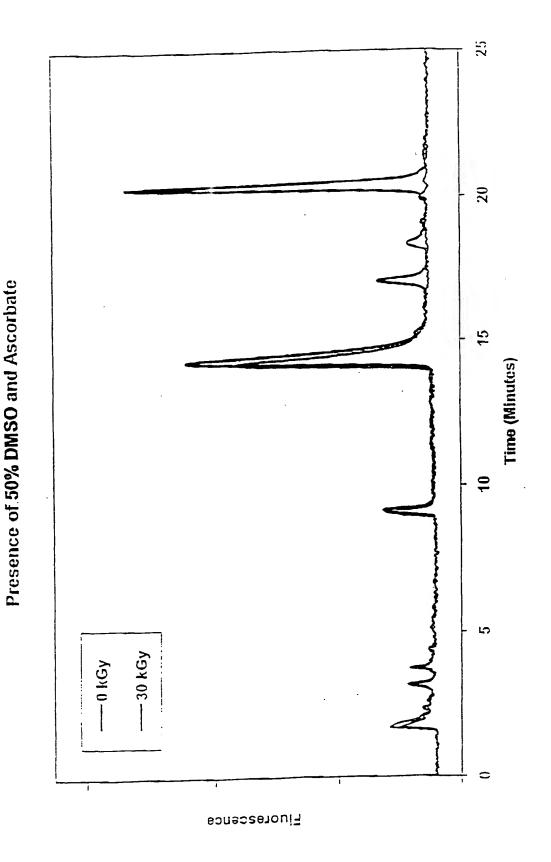
(A)

Gamma Irradiation of Hydralyzed Heart Valve Cusps in the Presence of 50% DMSO



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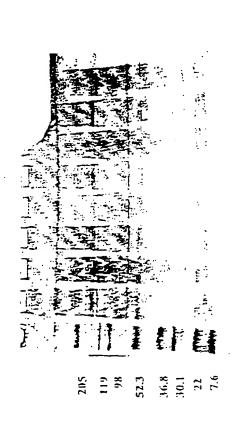
Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the



## **Gamma Irradiation of Porcine Heart Valve**

Cusps in the Presence of Various Solvents

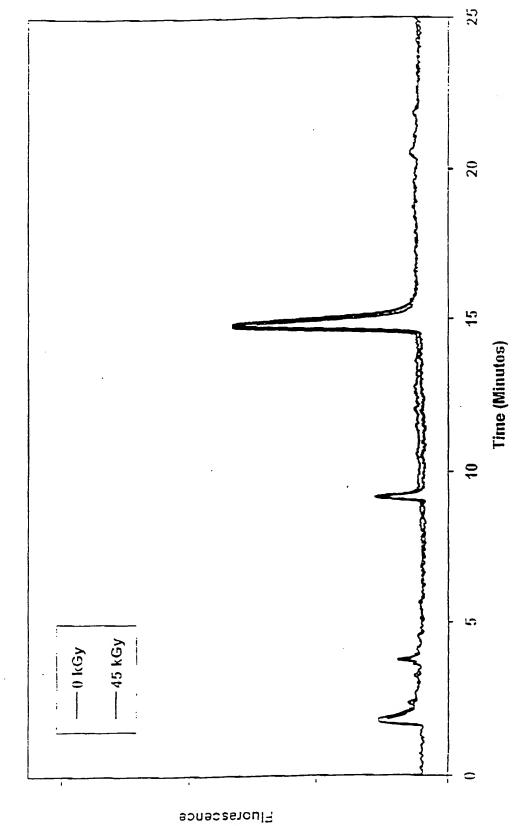
Reduced



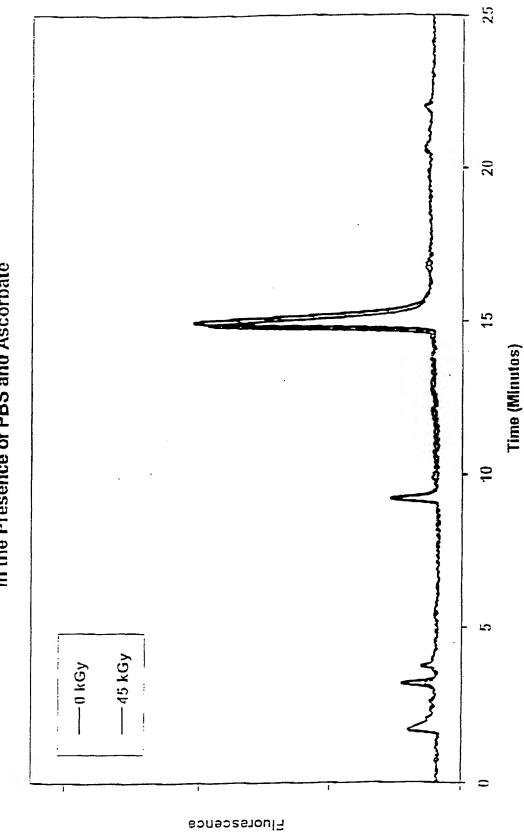
- 1. Molecular Weight Markers
- 2. Cryoproservative, 0 kGy 3. Cryoproservative, 30 kGy
- 4. PBS, 0 kGy 5. PBS, 30 kGy
- 6. 50% DMSO, 0 kGy 7. 50% DMSO, 30 kGy
- 8. 50% DMS0 and Ascorbate, 0 kGy 9. 50% DMS0 and Ascorbate, 30 kGy

5

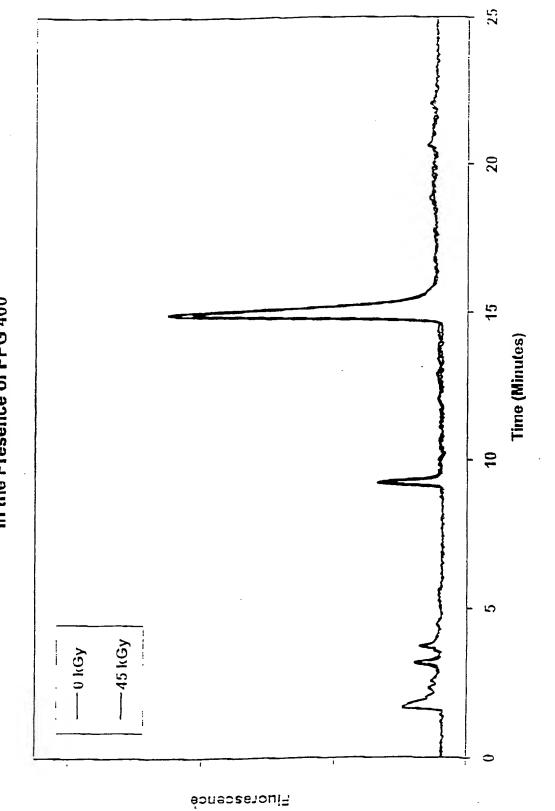
Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS



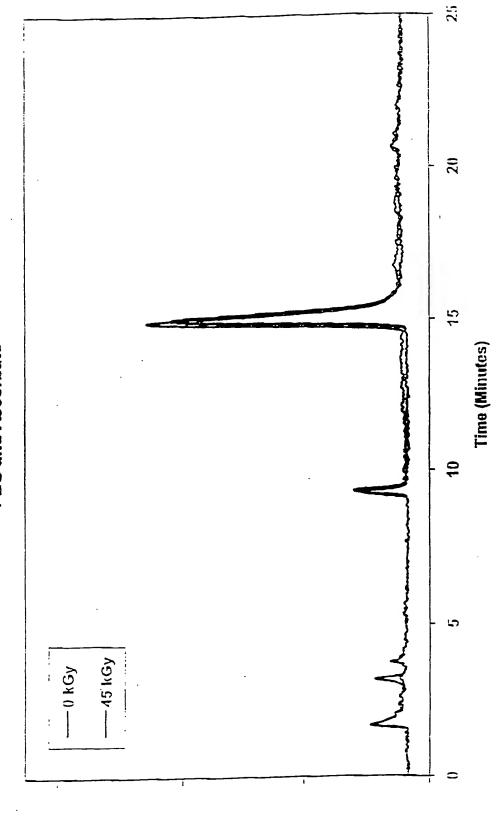
Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS and Ascorbate



Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400

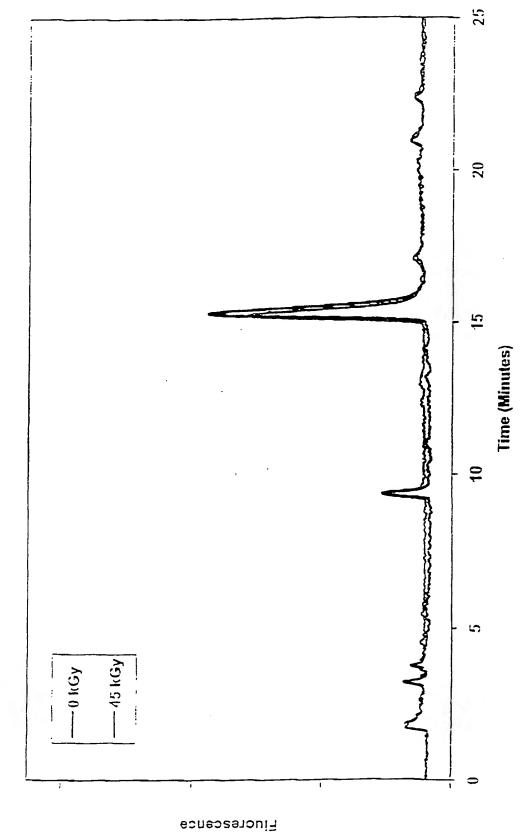


Gamma Irradiation of Hydrolyzed Heart Valve Cusps Dehydrated with PPG 400 and Rehydrated in the Presence of **PBS and Ascorbate** 



Fluorescence

Samma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO



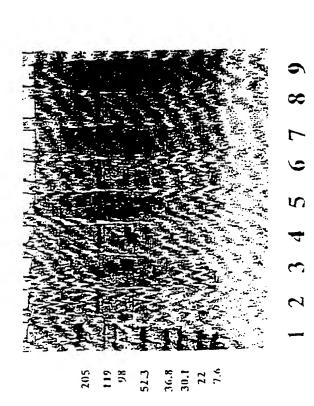
25 Gamma Irradiation of Hydrolyzed Heart Valve Cusps 20 in the Presence of 50% DMSO and Ascorbate 15 Time (Minutes) S -45 kGy -0 kGy

Fluorescance ;

74

## COLLETT BARELOR

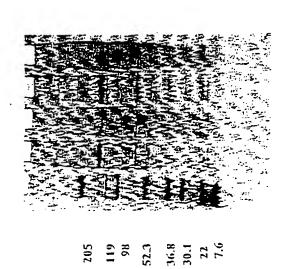
## **Gamma Irradiation of Porcine Heart** Valve Cusps in the Presence of Various Solvents



- 1. Molecular Weight Markers
- 2. PBS, 0 kGy
- 3. PBS, 45 kGy
- 4. PBS and Ascorbate, 0 kGy
- 5. PBS and Ascorbate, 45 kGy
- 6. PPG400, 0 kGy
- 7. PPG400, 45 kGy
- 8. Dohydrated in PPG400 and Rehydrated with PBS and Ascorbate, 0 kGy
- 9. Dehydrated in PPG400 and Rehydrated with PBS and Ascorbate, 45 kGy

## ngerage antion

## **Gamma Irradiation of Porcine Heart** Valve Cusps in the Presence of Various Solvents

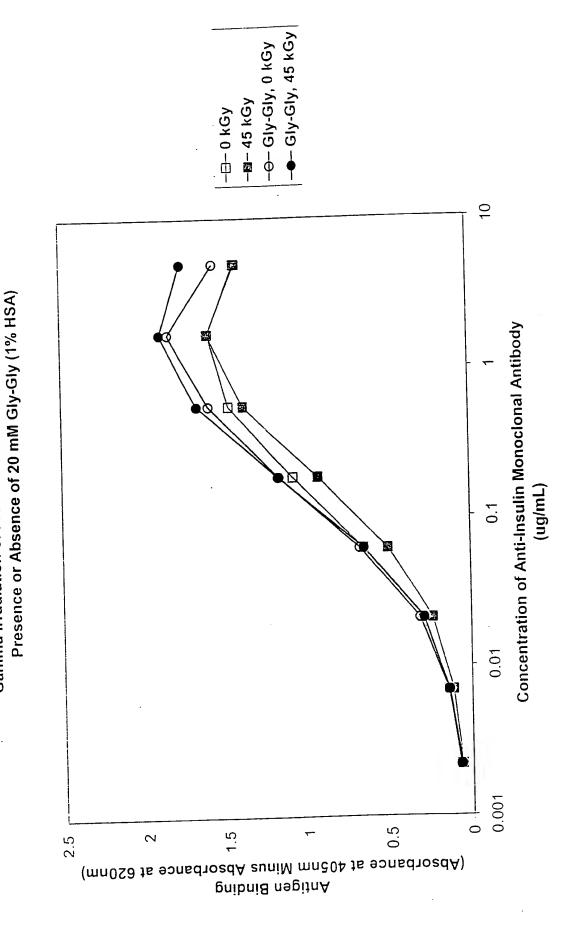


- 1. Molecular Weight Markers
- 2. 50% DMSO, 0 kGy
- 3. 50% DMSO, 45 kGy
- 4. 50% DMSO and Ascorbate, 0 kGy
- 5. 50% DMSO and Ascorbate, 45 kGy

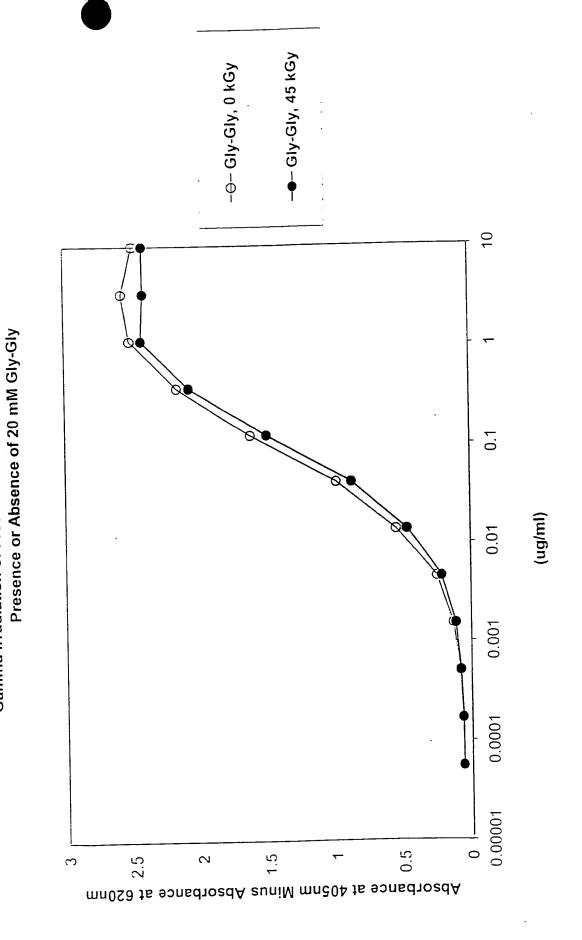
7

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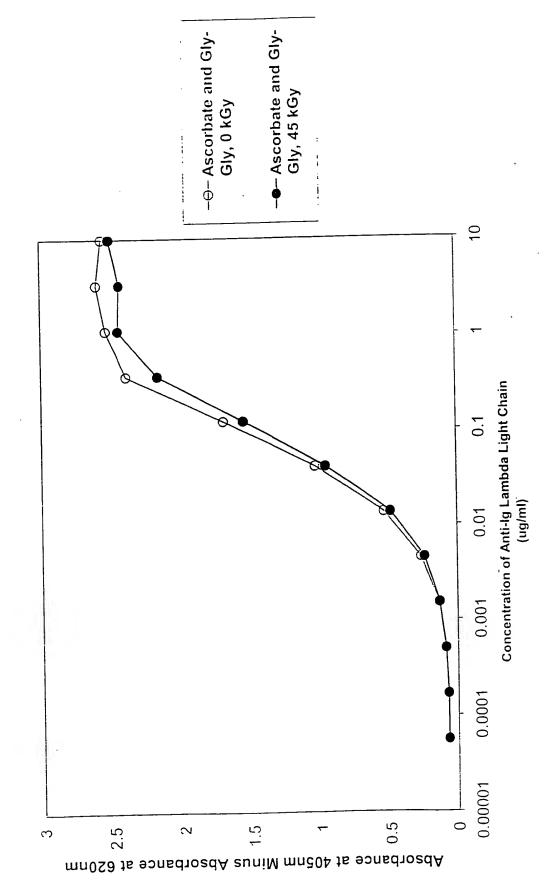
Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody in the



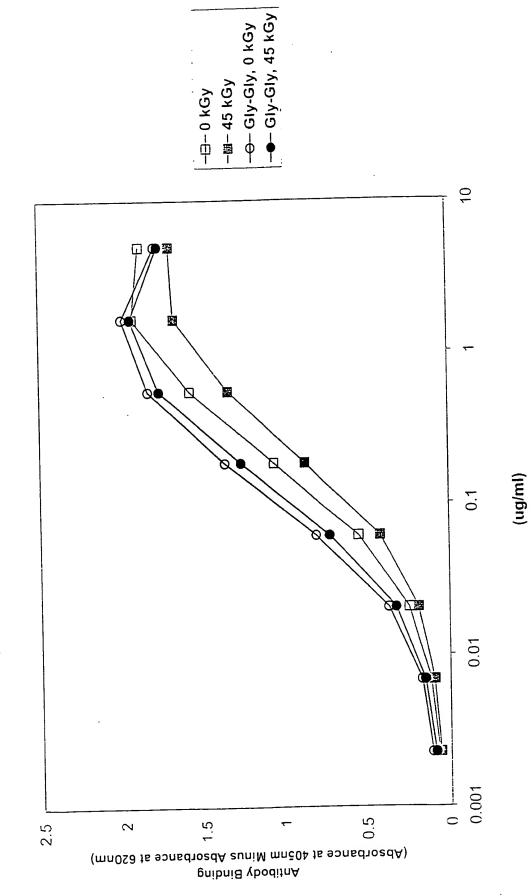
Gamma Irradiation of Freeze-Dried Anti-Human Ig, Lambda Light Chain, in the



Gamma Irradiation of Freeze-Dried Anti-Human Ig, Lambda Light Chain, in the Presence or Absence of 20 mM Ascorbate and 20 mM Gly-Gly



Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody in the Presence or Absence of 20 mM Gly-Gly (and 1% BSA)

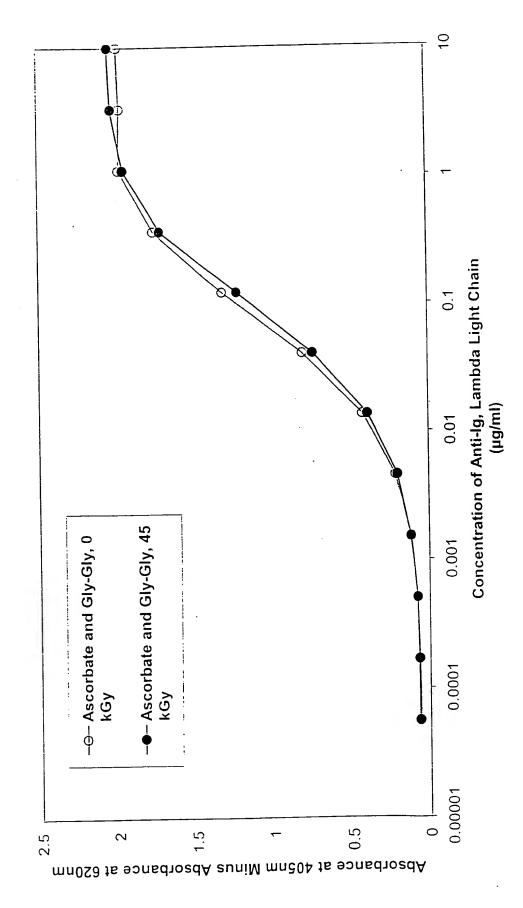


194

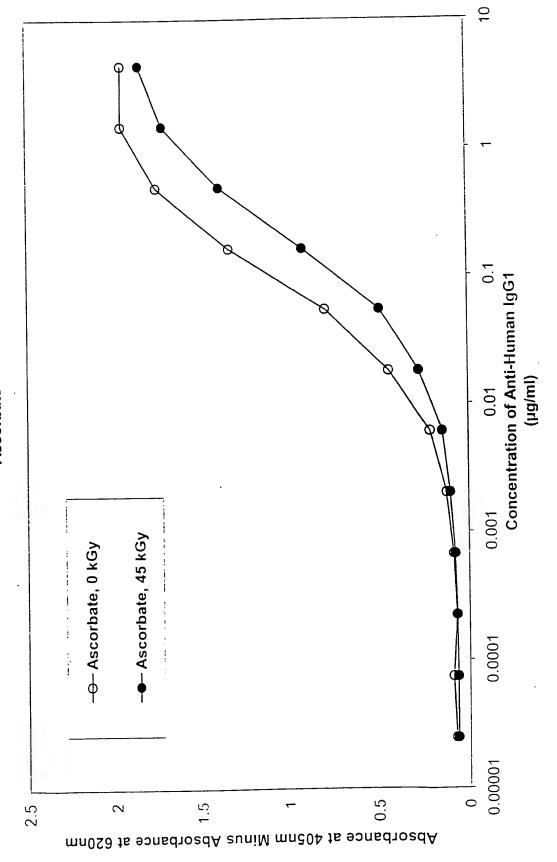
Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate -⊖- Ascorbate, 0 kGy

10 0.001 0.01 0.01 0.01 0.01 Concentration of Anti-Ig Lambda Light Chain (µg/ml) --- Ascorbate, 45 kGy 0.0001 0.00001 0.5 1.5 2.5 2 Absorbance at 405nm Minus Absorbance at 620nm

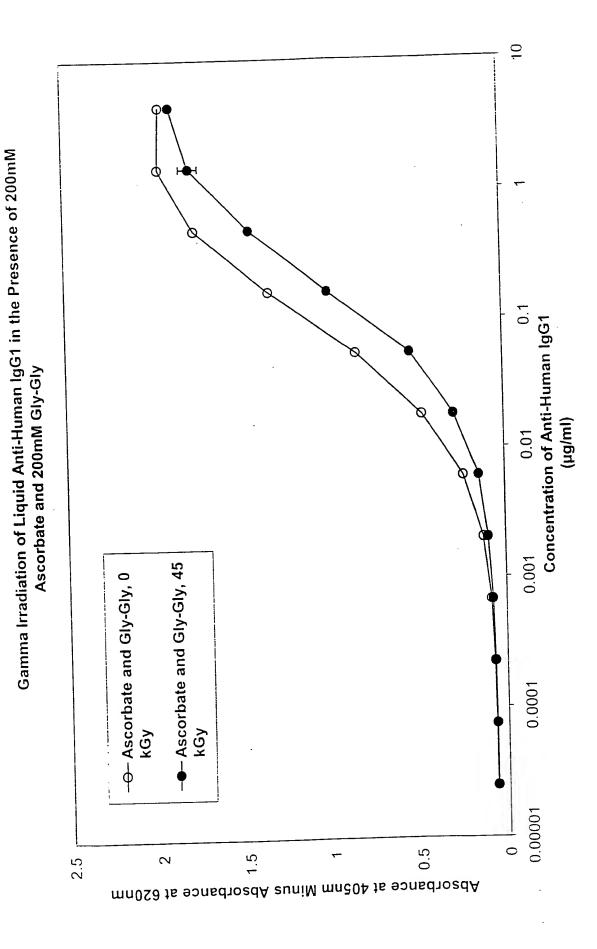
Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate and 200mM Gly-Gly



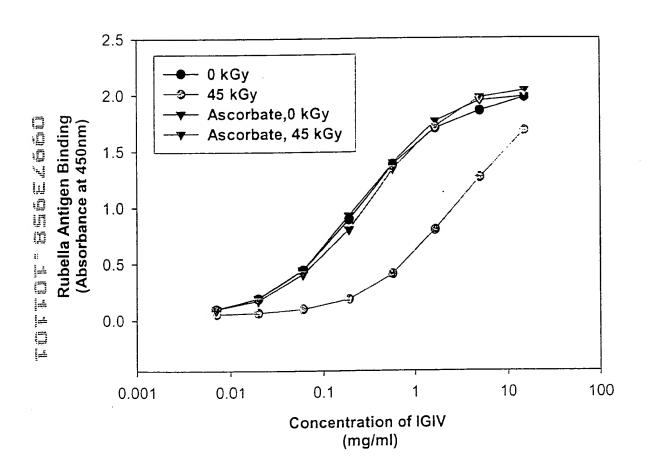
Gamma Irradiation of Liquid Anti-Human IgG1 in the Presence of 200mM Ascorbate



Q 6)

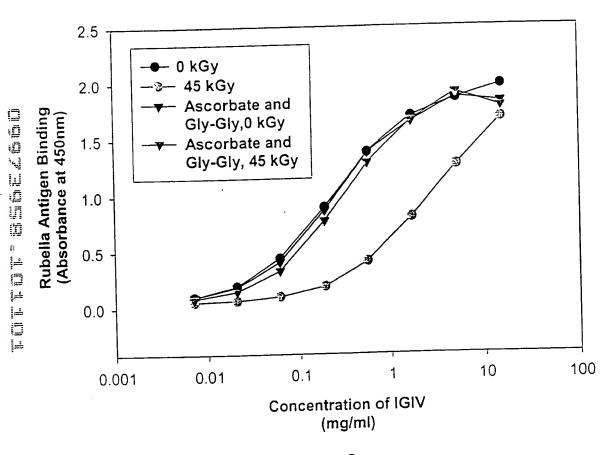


Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate Using Rubella IgG Assay



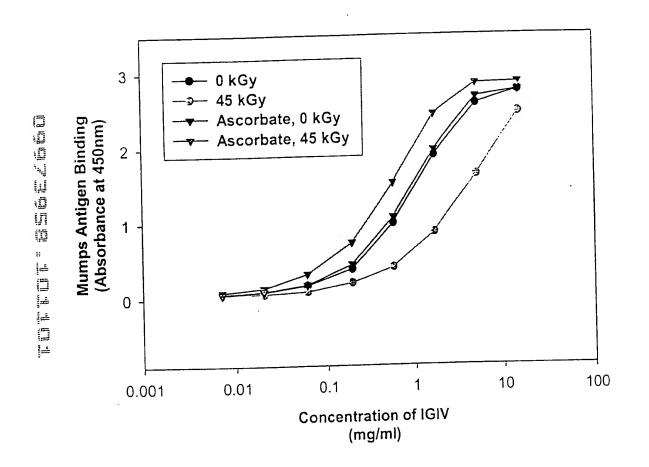
20A

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Using Rubella IgG Assay



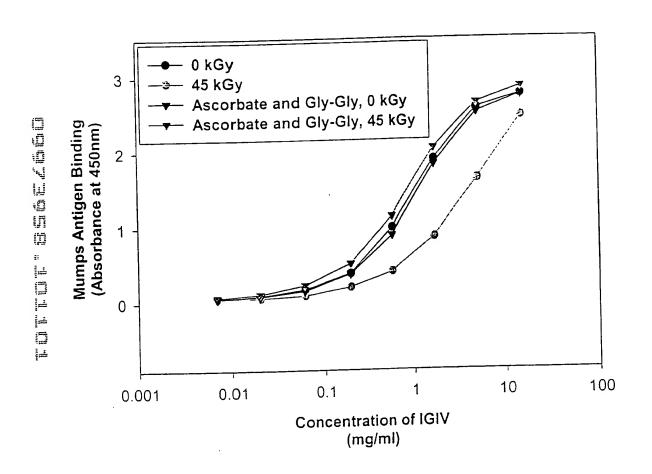
20 B

Gamma Irradiation of Liquid
IGIV in the Presence or Absence of 200 mM Ascorbate
Using Mumps Assay



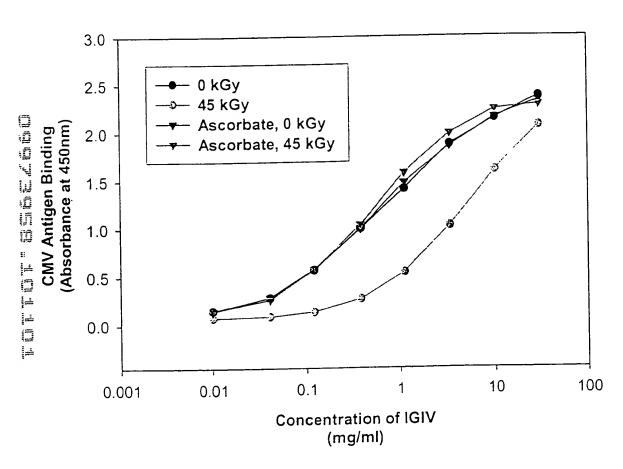
20C

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Using Mumps Assay



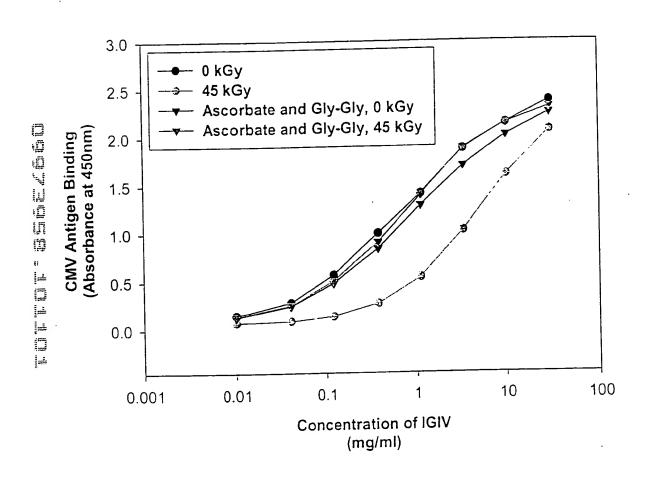
200

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate Using CMV Assay



20É

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Using CMV Assay

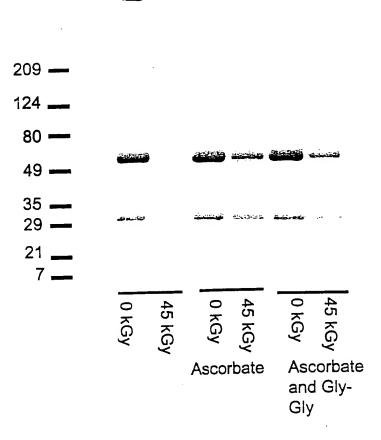


20F

### SDS-PAGE of

### Liquid IGIV

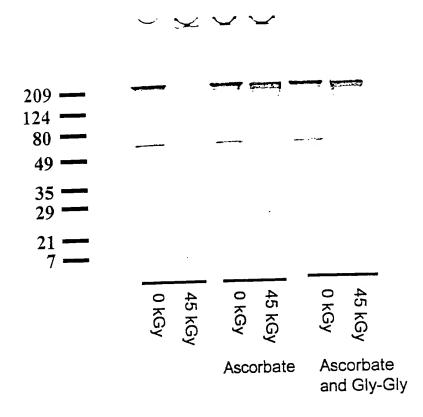
Liquid IGIV, Reduced 5-15%



### SDS-PAGE of

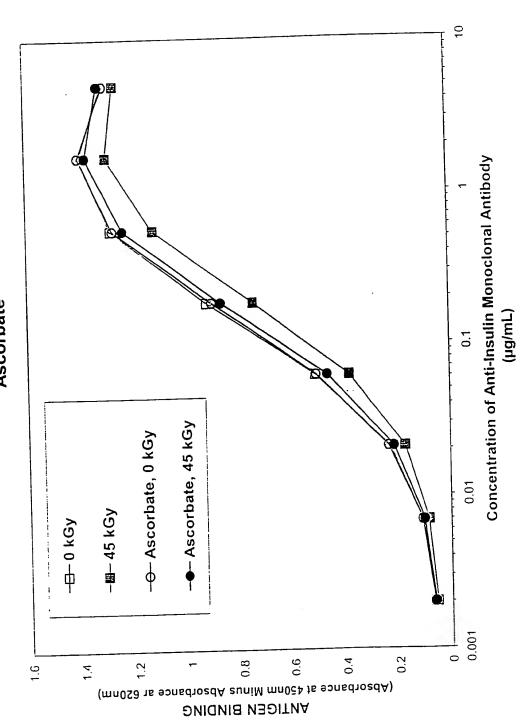
### Liquid IGIV

Liquid IGIV, Non-Reduced 5-15%

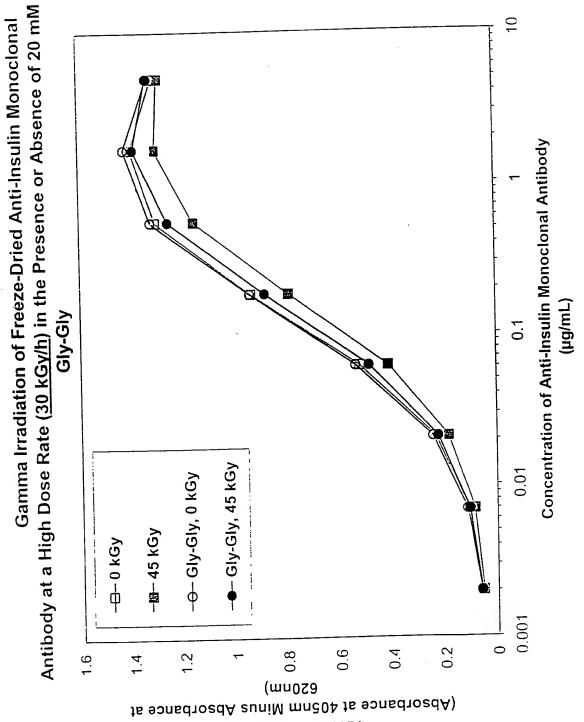


20H

Antibody at a High Dose Rate (30 kGy/h) in the Presence or Absence of 20 mM Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal **Ascorbate** 

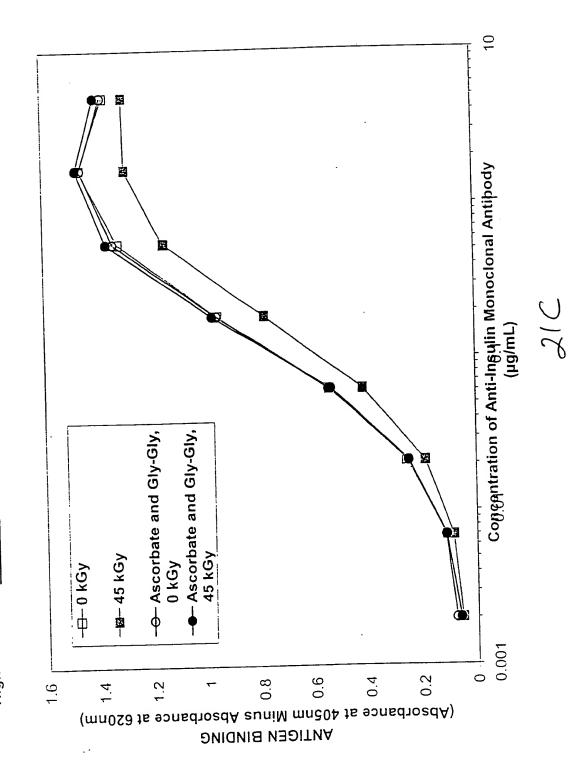


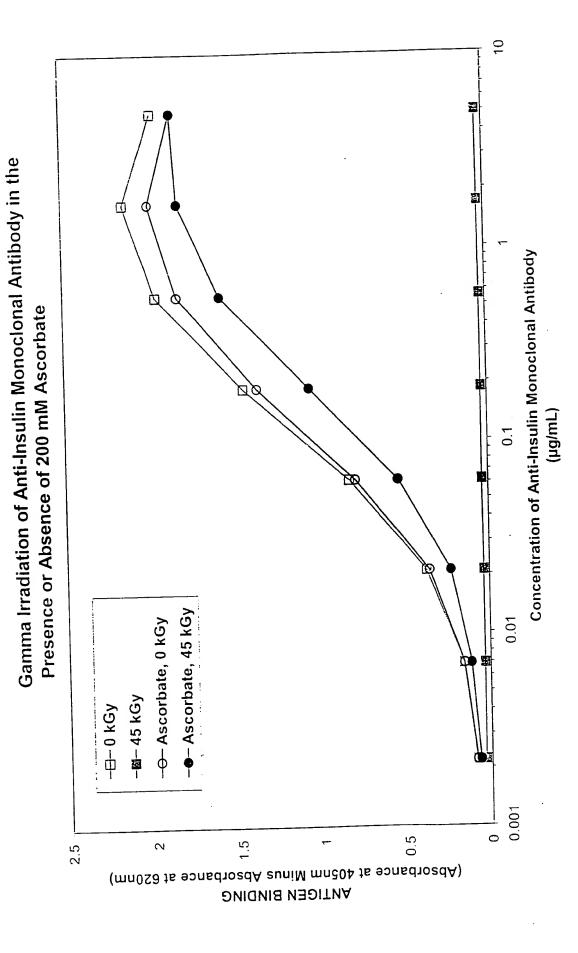
2/4



ANTIGEN BINDING

High Dose Rate 30 kGy/h in the Presence or Absence of 20 mM Ascorbate and 20 mM Gly-Gly Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a





Gamma Irradiation of Anti-Insulin Monoclonal Antibody in the

10 Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Concentration of Anti-Insulin Monoclonal Antibody (hg/mL) --- Ascorbate and Gly-Gly, 0 kGy —配—45 kGy ⊕ 0 kGy 0.001 (Absorbance at 405nm Minus Absorbance at 620nm)  $\frac{1}{5}$ 2.5 **ANTIGEN BINDING** 

# SDS-PAGE for a Glycosidase

Nonreduced

Reduced

20 30

20

3

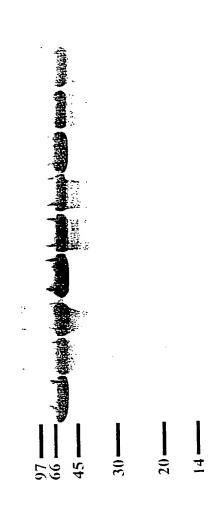
7

5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy	Ascorbate nd Gly-Gly
0 kGy	Asi
5.4 <b>k</b> Gy/hr, 45 kGy	bate
1.7 kGy/hr, 45 kGy 0 kGy	Ascorbate
5.4 kGy/hr, 45 kGy	
1.7 kGy/hr, 45 kGy 0 k <b>G</b> y	

and Gly-Gly Ascorbate 5.4 **k**Gy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy Ascorbate 5.4 **k**Gy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy 1.7 **k**Gy/hr, 45 kGy 0 kGy

## SDS-PAGE for a Sulfatase

### S-FAGE TOF a S Reduced

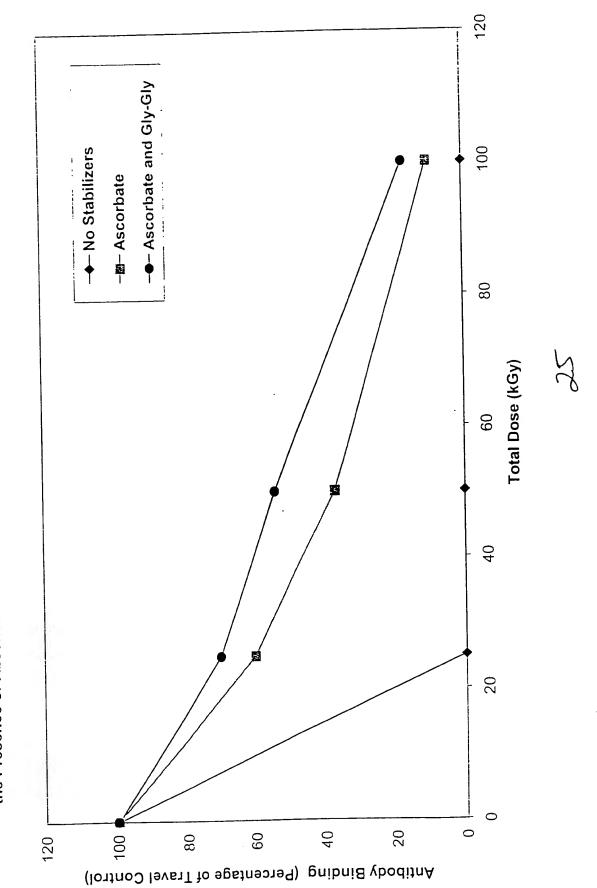


5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 445 kGy 0 kGy	Ascorbate and Gly-Gly	CC
5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy	Ascorbate	
5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy	٠	
0 kGy		

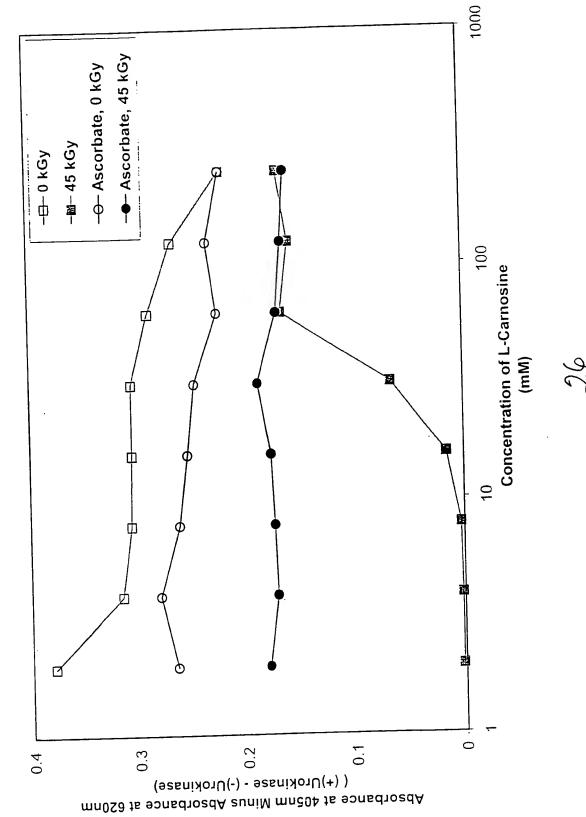
35 -Ascorbate and Gly-Gly, 5.4 kGy/hr, 45 kGy Gamma Irradiation of a Glycosidase In the Presence or Absence of 30 ... ... Ascorbate, 1.7 kGy/hr, 45 kGy -Ascorbate and Gly-Gly, 0 kGy 25 - 5.4 kGy/hr, 45 kGy Ascorbate Alone or In Combination with Gly-Gly Enlargement of Peak at 30-32 Minutes 20 Time (Minutes) Ascorbate and Gly-Gly, 1.7 kGy/hr, 45 kGy 5 Ascorbate, 5.4 kGy/hr, 45 kGy 9 Ascorbate, 0 kGy -100000 30 300000 700000 1100000 1500000 ..... 0 kGy 200000 400000 1000000 21loVm 800000 1400000 000009 1600000 1200000

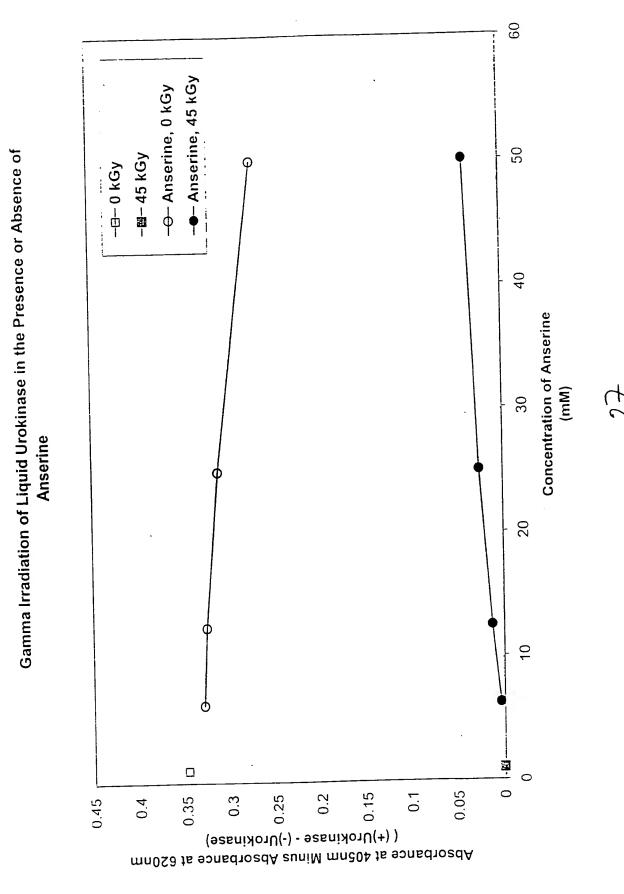
74

the Presence or Absence of 200 mM Ascorbate Alone or in Combination With 200 mM Gly-Gly Gamma Irradiation of Liquid Anti-Insulin Monoclonal Antibody in

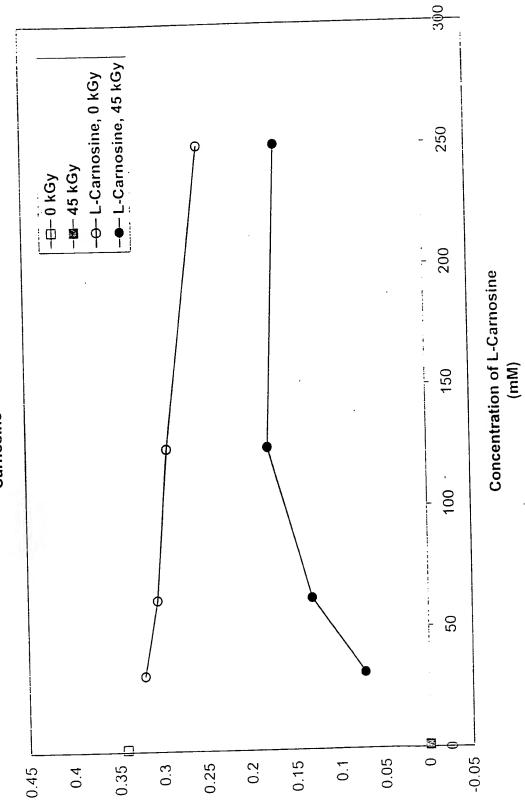


Gamma Irradiation of Liquid Urokinase, With L-Carnosine, at 45 kGy in the Presence or Absence of 50mM Ascorbate

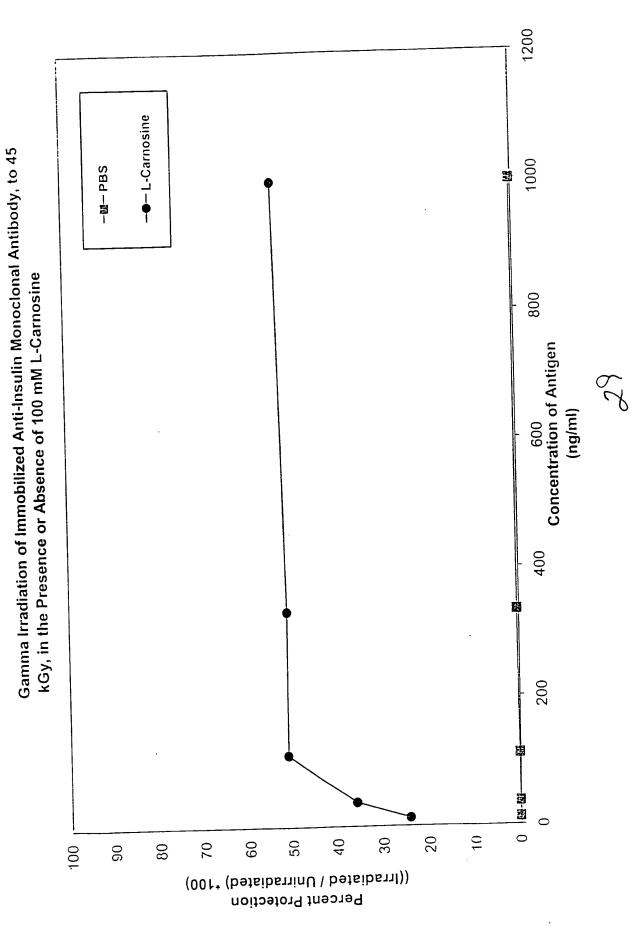




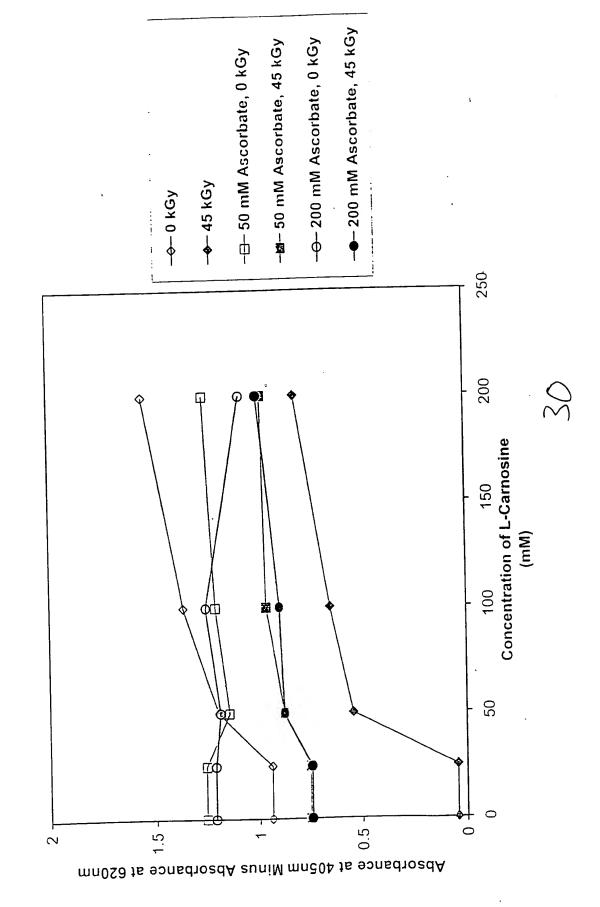
Gamma Irradiation of Liquid Urokinase in the Presence or Absence of L-Carnosine



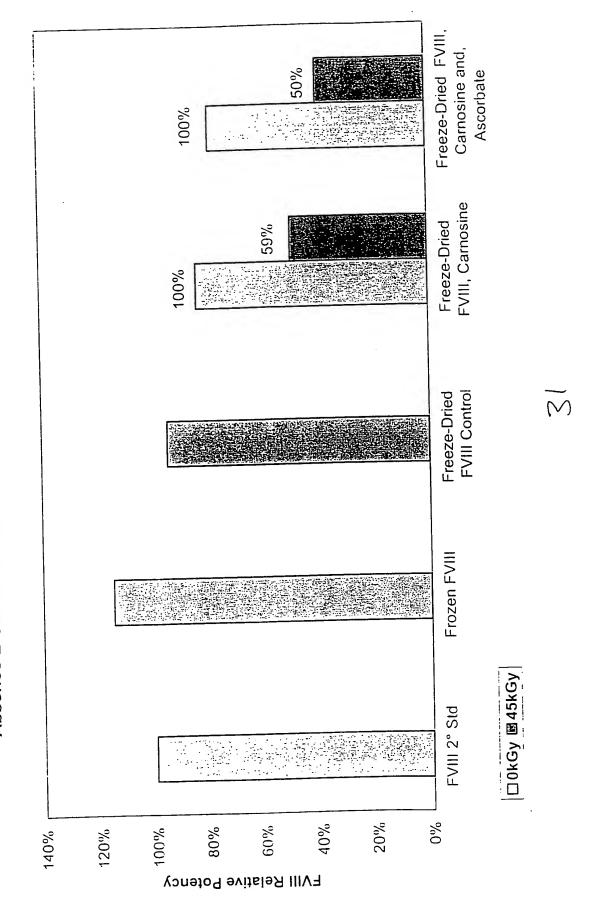
( (+)Urokinase - (-)Urokinase) Absorbance at 405nm Minus Absorbance at 620nm



Gamma Irradiation of Immobilized Monoclonal Antibody in the Presence or Absence of L-Carnosine and Ascorbate

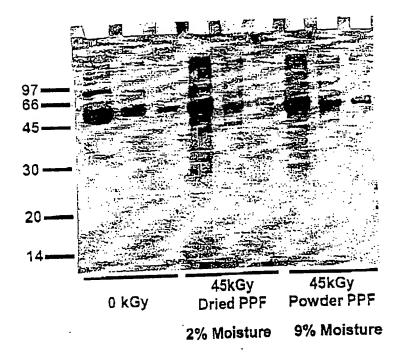


Gamma Irradiation of Freeze-Dried FVIII in the Presence or Absence L-Carnosine Alone or in Combination with Ascorbate

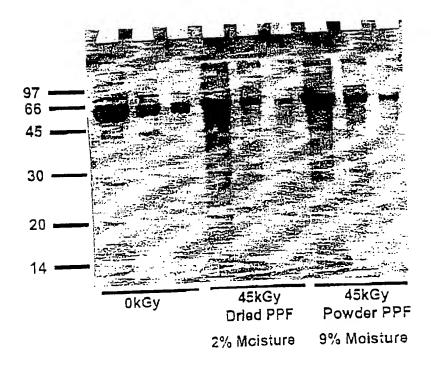


### Gamma Irrac. Son of Dried and Powder PPF

### Nonreduced, 12.5 /



**Reduced**, 12.5%



12 Gamma Irradiation of Dried and Powder PPF 10 –45 kGy, Powder PPF (9% Moisture) -45 kGy, Dried PPF (2% Moisture) · 0 kGy, Dried PPF (2 % MoIsture) 0 ABSORBANCE at 280nm (Microvolta) 100 300

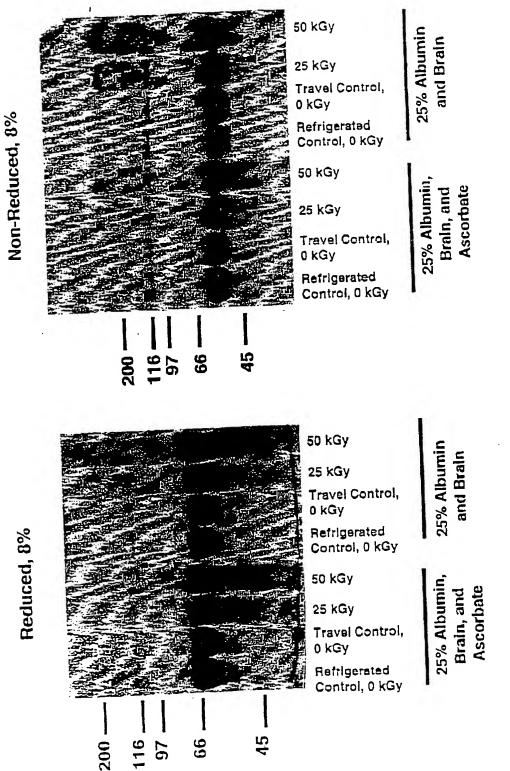
328

TIME (Minutes)

SKOS. 2500 Gamma Irradiation of Dried and 20KK) Time (s) 1500 1550 Powder PPF Enlargement of Peak Between 1350 -45 kGy, Powder PPP (9% Moisture) 200 --- 45 kGy, Dried PPF (2% Moisture) and 1550 Seconds 1450 **2**00 560 -0kGy 1350 12000 1800 -50000 25007m . 950000 450000 1950000 1450000

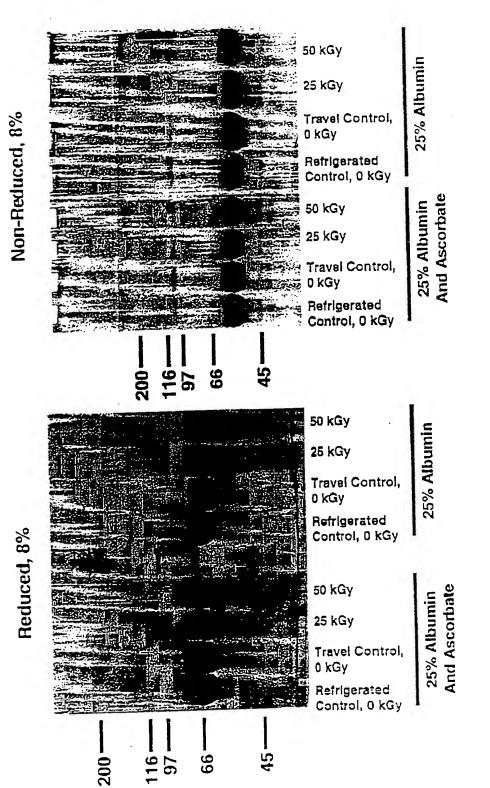
326

Gamma Irradiation (to 25 and 50 kGy) of 25% Albumin in the Presence of Brain Alone or in Combination with 200 mM Ascorbate



35A

Gamma Irradiation (to 25 and 50 kGy) of 25% Albumin in the Presence or Absence of 200 mM Ascorbate



Gamma Irradiation of 25% Albumin in the Presence

18 16 14 12 of Brain and 200 mM Ascorbate 10 Time (Minutes) 9 ..... 50 kGy -25 kGy -0 kGy 0 5000 -15000 10000 20000 Absorbance (mVolts)

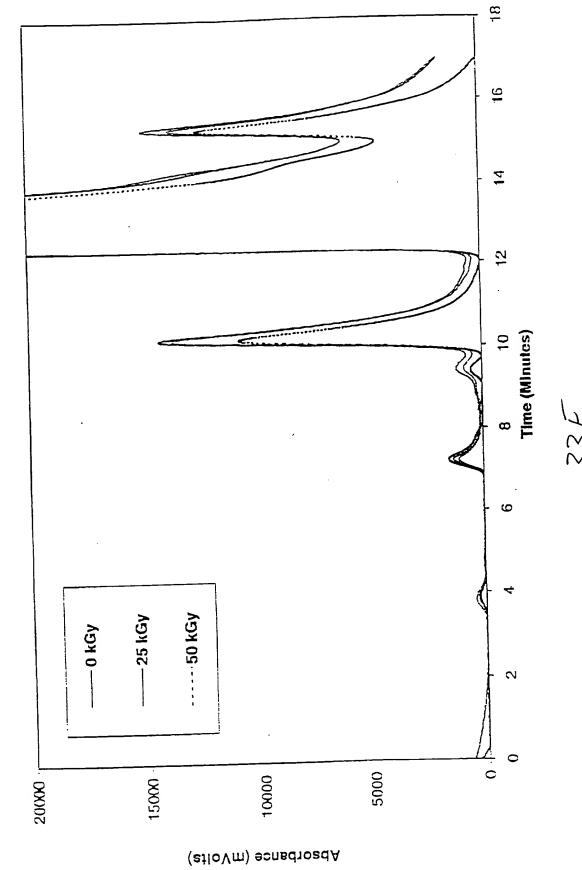
33(

Gamma Irradiation of 25% Albumin

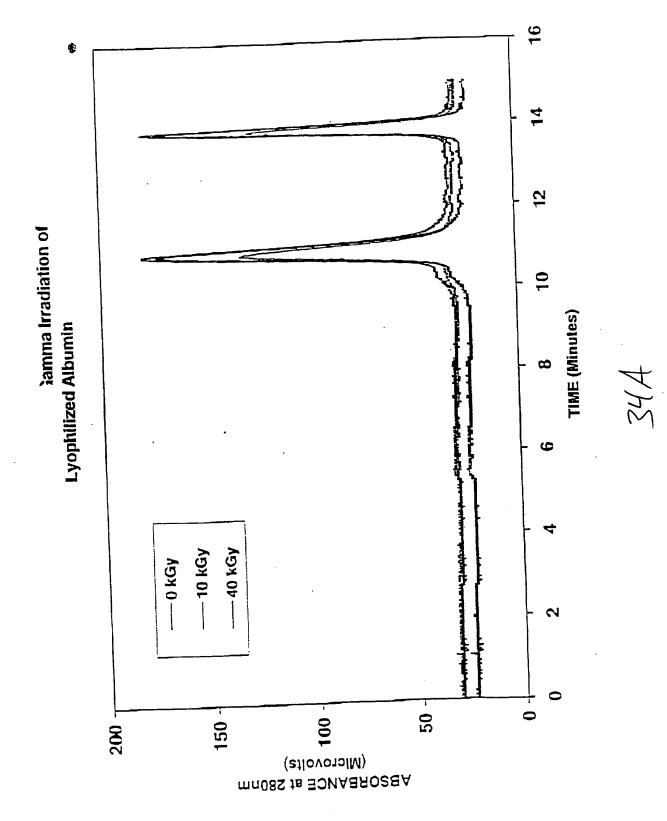
in the Presence of Brain

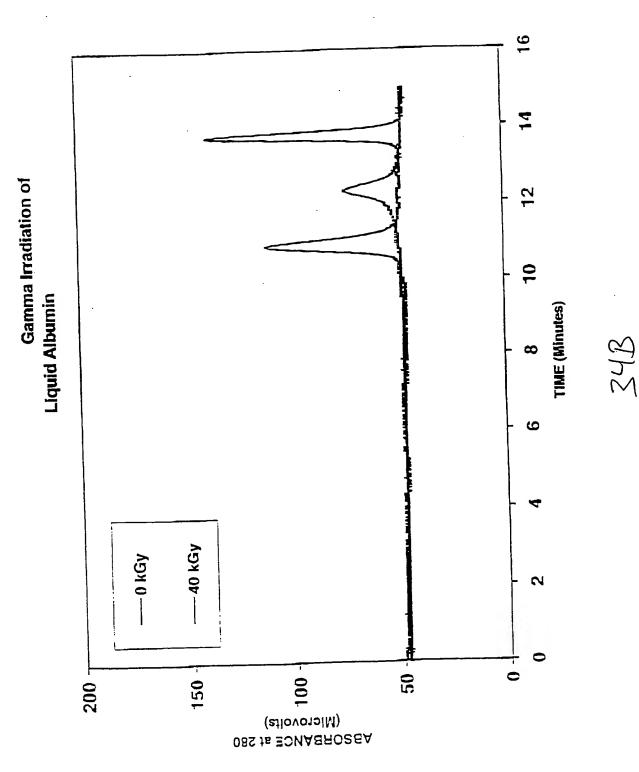
18 16 12 Time (Minutes) ပ -25 kGy ----50 kGy -0 kGy  $\alpha$ 5000 10000 15000 -20000 Apsorbance (myolts)

Gamma Irradiation of 25% Albumin in the Presence of 200 mM Ascorbate



18 16 <del>†</del> 12 **Gamma Irradiation of** 25% Albumin 10 Time (Minutes) 9 -25 kGy ----50 kGy -0 kGy 2 0 Absorbance (mVolts) 5000 15000 20000





# 25% Albumin - Non-Reduced 1 2 3 4 5 6 7 8 9 10 11 12

Std   Lane   Empty			•				
200 3 Empty 116 4 0 Kgy (Control) Box 3C (- Ar) 12				Stċ	<u>Lane</u>	Sample	2 CA
200 3 Empty 116 4 0 Kgy (Control) Box 3C (-Ar) 97 5 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (-Ar) 97 5 18.0 Kgy (≈0.92 Kgy/hr) Box 2 (-Ar) 45 7 30.4 Kgy (≈1.01 Kgy/hr) Box 3 (-Ar) 8 0 Kgy (Control) Box 3C (-Ar) 31 9 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (-Ar) 21.5 10 23.0 Kgy (≈0.92 Kgy/hr) Box 1 (-Ar) 12 Empty 13 12 Empty 14 11 30.4 Kgy (≈1.01 Kgy/hr) Box 3 (-Ar) 15 Empty 16 25% Albumin - Reduced 1 2 3 4 5 6 7 8 9 10 11 12 17 Std Lane Sample 18 Kd 1 Empty 2 Broad Range Std. (BioRad) 200 3 Empty 116 4 0 Kgy (≈0.91 Kgy/hr) Box 1 (-Ar) 116 4 0 Kgy (≈0.91 Kgy/hr) Box 2 (-Ar) 116 4 0 Kgy (≈0.91 Kgy/hr) Box 1 (-Ar) 116 4 0 Kgy (≈0.91 Kgy/hr) Box 1 (-Ar) 117 Std Kgy (≈0.91 Kgy/hr) Box 3C (-Ar) 118 0 Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 119 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 110 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 111 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 112 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 113 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 114 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 115 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 116 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 117 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 118 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 119 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar) 110 Std Kgy (≈0.91 Kgy/hr) Box 3 (-Ar)		-	<i></i>	<u>Kd</u>	1	Empty	22/1
116					2	Broad Range Std. (BioRad)	
116		<u> </u>		200	3	Empty	
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Empty   2   Broad Range Std. (BioRad)   200   3   Empty   200   3   Empty   3   116   4   0   Kgy (Control) Box 3C (-Ar)   4   16   66   6   23.0   Kgy (≈0.91   Kgy/hr) Box 1 (+Ar)   45   7   30.4   Kgy (≈0.92   Kgy/hr) Box 3 (-Ar)   8   0   Kgy (Control) Box 3C (-Ar)   31   9   18.0   Kgy (≈0.91   Kgy/hr) Box 1 (-Ar)   31   9   18.0   Kgy (≈0.91   Kgy/hr) Box 1 (-Ar)   31   9   18.0   Kgy (≈0.91   Kgy/hr) Box 1 (-Ar)   31   31   31   31   31   32   33   34   34   34   34   34   34				1 2	3 4	5 6 7 8 9 10 11 12	
Empty   2   Broad Range Std. (BioRad)   200   3   Empty   200   3   Empty   3   116   4   0   Kgy (Control) Box 3C (-Ar)   4   16   66   6   23.0   Kgy (≈0.91   Kgy/hr) Box 1 (+Ar)   45   7   30.4   Kgy (≈0.92   Kgy/hr) Box 3 (-Ar)   8   0   Kgy (Control) Box 3C (-Ar)   31   9   18.0   Kgy (≈0.91   Kgy/hr) Box 1 (-Ar)   31   9   18.0   Kgy (≈0.91   Kgy/hr) Box 1 (-Ar)   31   9   18.0   Kgy (≈0.91   Kgy/hr) Box 1 (-Ar)   31   31   31   31   31   32   33   34   34   34   34   34   34							
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116 4 0 Kgy (Control) Box 3C (- Ar)  97 5 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (+ Ar)  66 6 23.0 Kgy (≈0.92 Kgy/hr) Box 2 (+ Ar)  45 7 30.4 Kgy (≈1.01 Kgy/hr) Box 3 (- Ar)  8 0 Kgy (Control) Box 3C (- Ar)  18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)					2	Broad Range Std. (BioRad)	
116 4 0 Kgy (Control) Box 3C (- Ar)  97 5 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (+ Ar)  66 6 23.0 Kgy (≈0.92 Kgy/hr) Box 2 (+ Ar)  45 7 30.4 Kgy (≈1.01 Kgy/hr) Box 3 (- Ar)  8 0 Kgy (Control) Box 3C (- Ar)  18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)	1			200	3	Empty	
97 5 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (+ Ar) 66 6 23.0 Kgy (≈0.92 Kgy/hr) Box 2 (+ Ar) 45 7 30.4 Kgy (≈1.01 Kgy/hr) Box 3 (- Ar) 8 0 Kgy (Control) Box 3C (- Ar) 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)				#2T	4	0 Kgy (Control) Box 3C (- Ar)	
66 6 23.0 Kgy (≈0.92 Kgy/hr) Box 2 (÷ Ar) 45 7 30.4 Kgy (≈1.01 Kgy/hr) Box 3 (÷ Ar) 8 0 Kgy (Control) Box 3C (- Ar) 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)				47	5	18.0 Kgy (≈0.91 Kgy/hr) Box 1 (÷ Ar)	
45 7 30.4 Kgy (≈1.01 Kgy hr) Box 3 (- Ar) 8 0 Kgy (Control) Box 3C (- Ar) 31 9 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)							
8 0 Kgy (Control) Box 3C (- Ar) 31 9 18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)				2			
31 9 18.0 Kgy (≈0.91 Kgy/hr) Box i (- Ar)				デー <del>キ</del> ン 製		0 Kgy (Control) Box 3C (- Ax)	
				:	-		
$21.5  ext{ } 10  ext{ } 23.0  ext{ Kgv} (\approx 0.92  ext{ Kgv/hr}) 30x 4 (= Ar)$					9 10	23.0 Kgv (≈0.92 Kgv/hr) Box 2 (- Ar)	

# 25% Albumin - Reduced

## 5 6 7 8 9 10 11 12

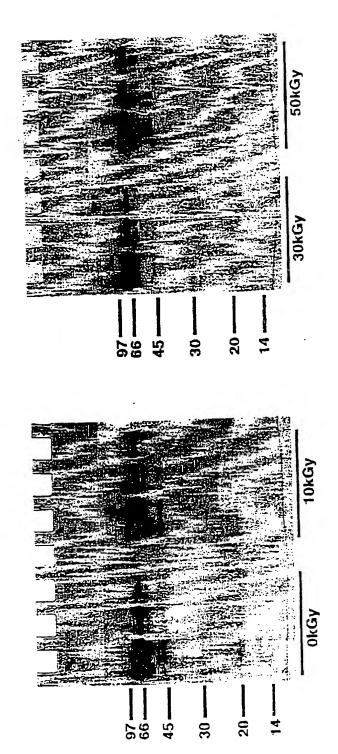
35B

Std	<u>Lane</u>	<u>Sample</u>
<u>Kd</u>	1	Empty
	2	Broad Range Std. (BioRad)
200	3	Empty
116	4	0 Kgy (Control) Box 3C (- Ar)
97	5	18.0 Kgy (≈0.91 Kgy/hr) Box 1 (÷ Ar)
66	6	23.0 Kgy (≈0.92 Kgy/hr) Box 2 (÷ Ar)
45	7	30.4 Kgy (≈1.01 Kgy hr) Box 3 (+ Ar)
	S	0 Kgy (Control) Box 3C (- Ar)
31	9	18.0 Kgy (≈0.91 Kgy/hr) Box 1 (- Ar)
21.5	10	23.0 Kgy (≈0.92 Kgy/hr) Box 2 (- Ar)

30.4 Kgy (≈1.01 Kgy/hr) Box 3 (- Ar) 14.4 11

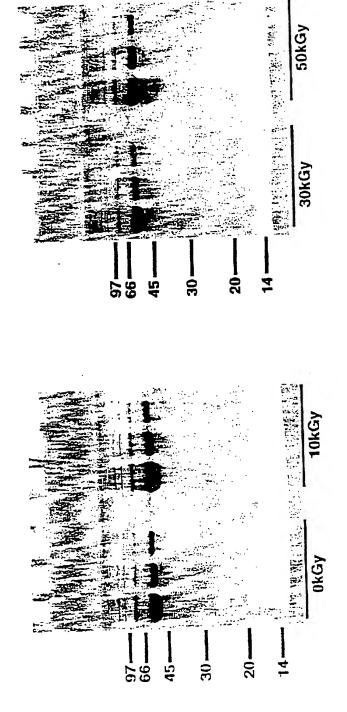
12 Empty.

Reduced



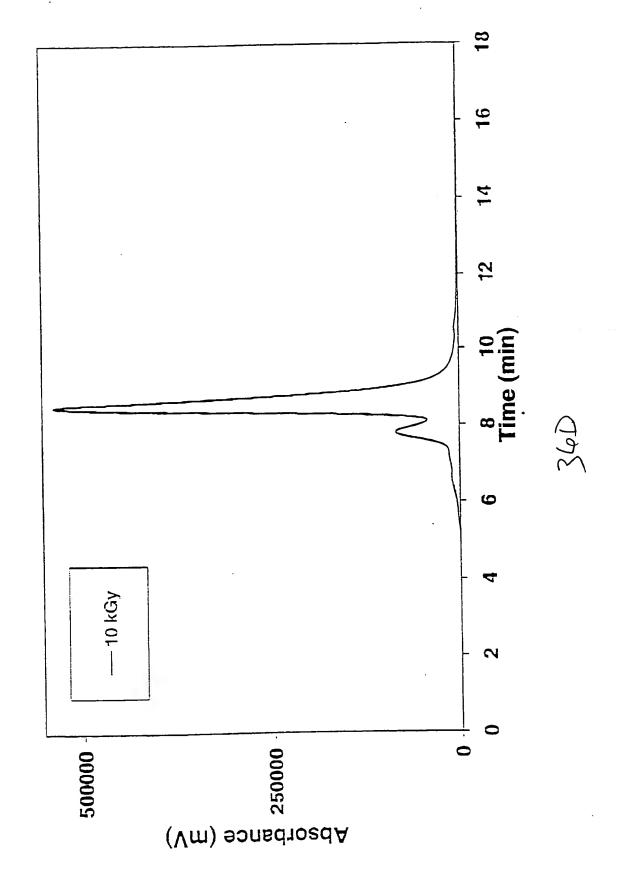
SGA

Nonreduced



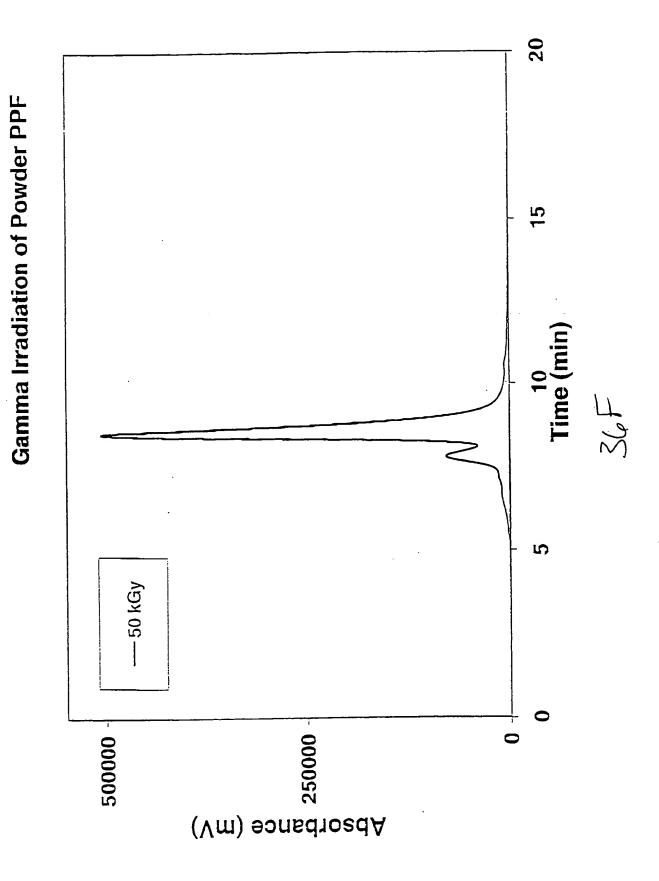
18 Gamma Irradiation of Powder PPF 16 14 8 10 Time (min) 36 C —0 kGy 8 (Vm) esorbance (mV) 250000 500000

Gamma Irradiation of Powder PPF



18 16 14 12 8 10 **Time (min)** -30 kGy Absorbance (mV) 500000

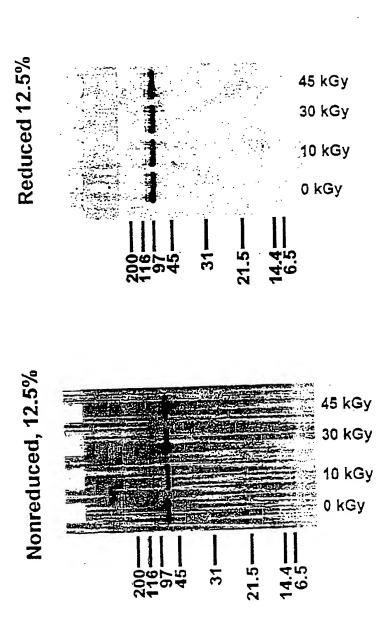
Gamma Irradiation of Powder PPF



50 Method 2 Gamma Irradiation of PPV in PPF by Irradiation at -80oC ■ Method 1 45 40 35 30 Radiation Dose (kGy) 25 20 15 10 2 TCID50 Viral Titer (Log10) ત က C

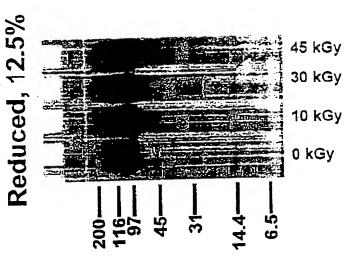
Yts

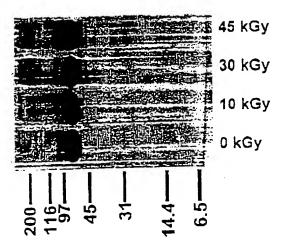
# Gamma Irradiation of PPF By Method 2



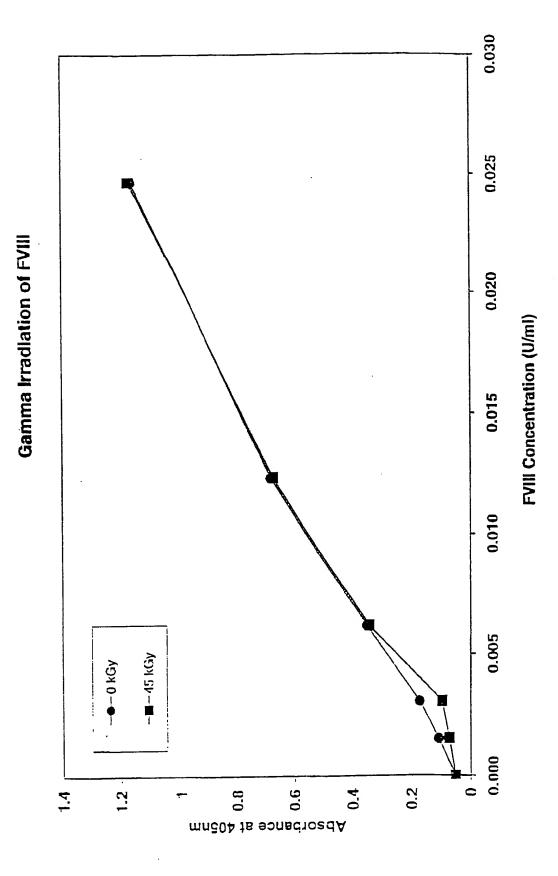
# 083101.alb.04/ 073001.jla.016 Gamma Irradiation of PPF By Method 1

of PPF By Method
Nonreduced, 12.5% Reduc





370



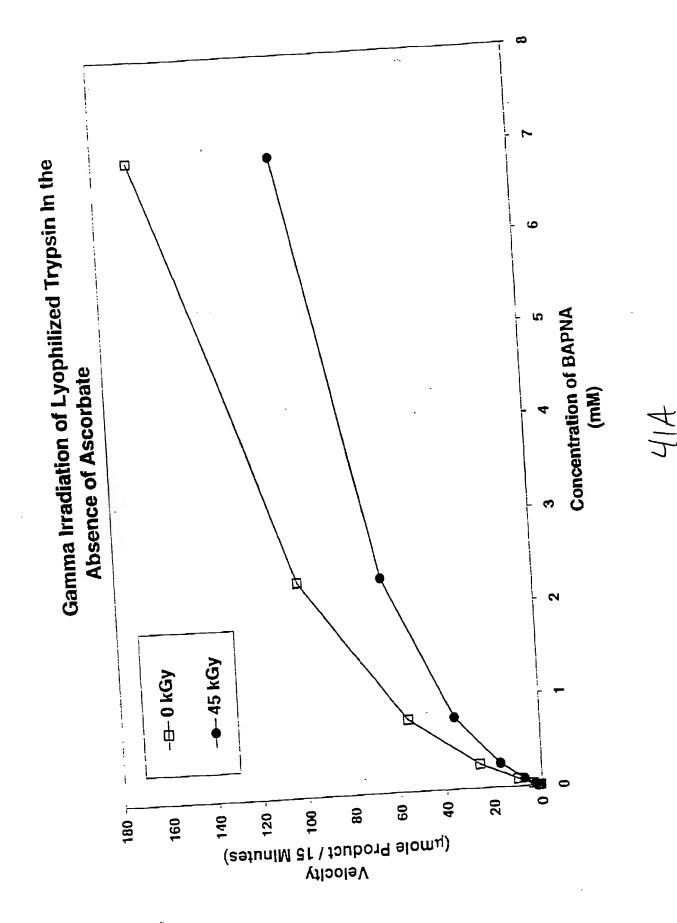
--- 45 kGy, 1.8% Water -∎- 45 kGy, 2.4% Water -ө-0 кGy, 1.8% Water -B- 0 kGy, 2.4% Water Gamma Irradiation of Lyophilized Trypsin In the 9 Concentration of BAPNA Absence of Ascorbate (MILL) 20 0 8 \$ Velocity (ymole Product / 15 Minutes) 5 5 8 8 6 180 . 160

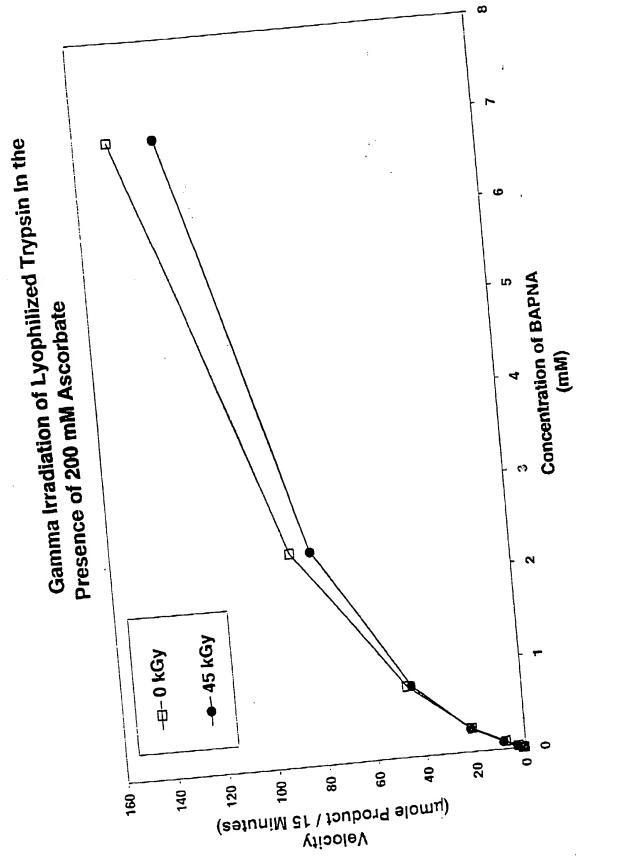
Gamma Irradiation of Lyophilized Trypsin In the

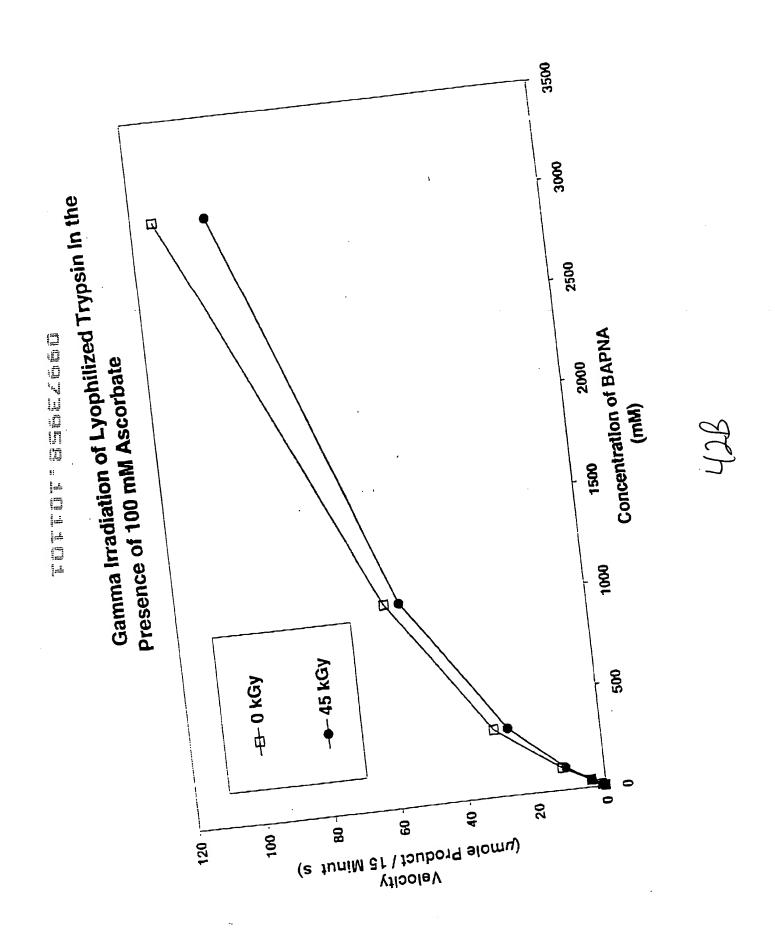
--- 45 kGy, 0.7% Water -∎- 45 kGy, 3.7% Water — 0 kGy, 0.7% Water -е-0 kGy, 3.7% Water 9 Ŋ Concentration of BAPNA Presence of 100 mM Ascorbate (Mm) Velocity
(prinole Product / 15 Minutes)

5 8 6 20 9 120 140 160

-B-Lyophilized --- Liquid Gamma Irradiation of Two Forms of Trypsin In the g Presence of 200 mM Ascorbate œ Hd Ŋ 40 -20 8 20 80 06 28 Percentage Recovery of Trypaln Activity







---45 kGy, 5.4% Water -**1**-45 kGy, 5.8% Water -ө-0 кGy, 5.4% Water -B-0 kGy, 5.8% Water Gamma Irradiation of Lyophilized Trypsin In the Concentration of BAPNA Absence of Ascorbate (mm) **50** 40 00 8 Velocity (umole Product / 15 Minutes) 3 5 5 8 8 160 200 180

434

-45 kGy, 1.1% Water -**-**-45 kGy, 2.8% Water -ө- 0 kGy, 1.1% Water -B- 0 kGy, 2.8% Water Gamma Irradiation of Lyophilized Trypsin In the 9 Concentration of BAPNA Presence of 100 mM Ascorbate (mM) ೩ 8 8 Velocity (eatuniM &t \ toubord elomy) \$\frac{2}{5} \quad \frac{2}{5} \quad \frac{2} ෂ 300 180

600 -- 45 kGy, 1.5mM Uric Acid -■-0 kGy, 1.5mM Uric Acid Gamma Irradiation of Liquid Trypsin In the Presence 58 -0-45 kGy 10 kGy of Increasing Concentrations of Ascorbate 48 Concentration of Ascorbate (mm) 300 **500** \$ (Absorbanc at 405nm Minus Absorbance at 620nm, 20 Minutes Minutes) 5 Trypsin Activity

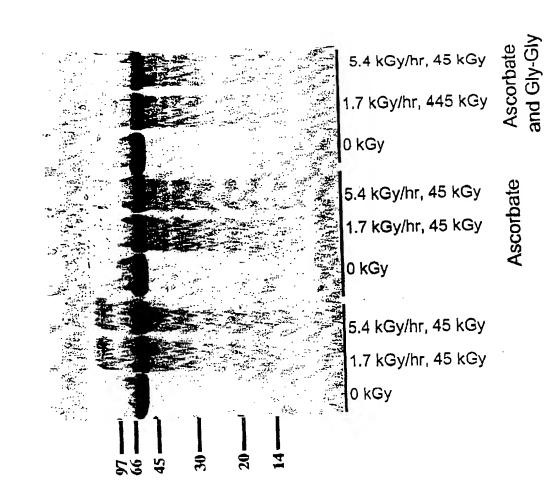
# HOA

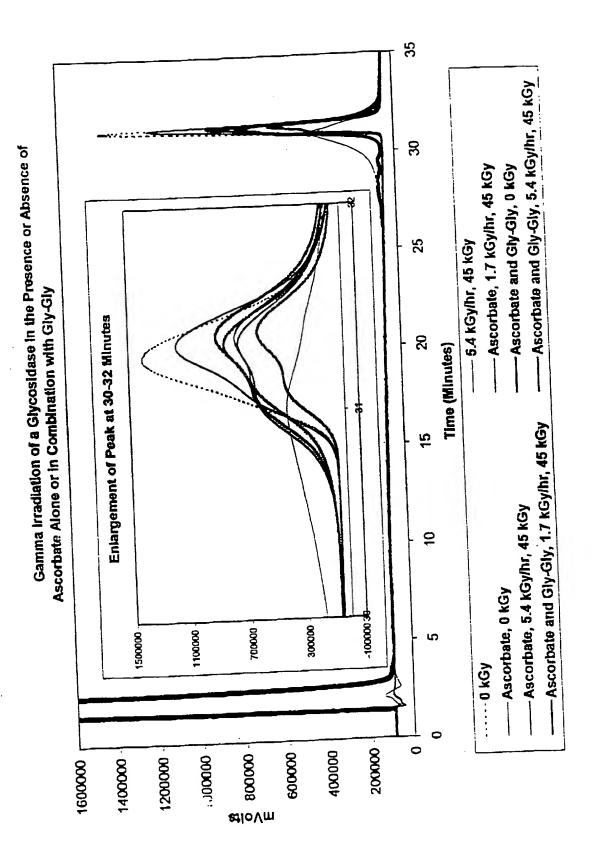
# and Gly-Gly Ascorbate 5.4 kGy/hr, 45 kGy SDS-PAGE for a Glycosidase 1.7 kGy/hr, 45 kGy 0 kGy Ascorbate 5.4 kGy/hr, 45 kGy Reduced 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy Ascorbate and Gly-Gly 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy Nonreduced 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy 5.4 kGy/hr, 45 kGy 1.7 kGy/hr, 45 kGy 0 kGy

8

# SDS-PAGE for a Sulfatse

# Reduced





Gamma Irradiation of a Lyophilized Glycosidase and Sulfatase In the Absence and Presence of 100mM Ascorbate

Sulfatase			45 kGy 0 kGy 45 kGy 0 kGy	With Ascorbate Without Ascorbate
Glycosidase .09—	24- 80- 49- <b>3</b> 5- 36-	21 <i>-</i> 7 <i>-</i>	45 kGy 0 kGy 45 kGy 0 kGy	1

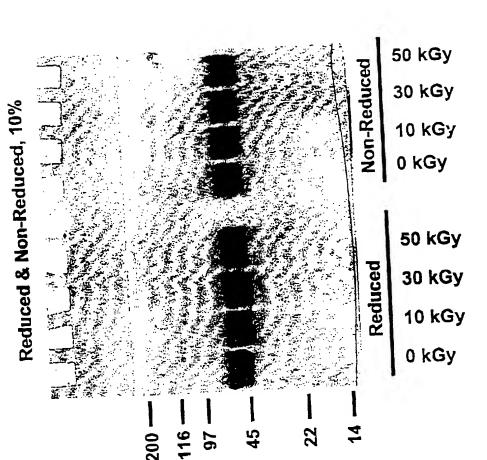
PAGFEGER ACTION

Gamma Irradiation of a Lyophilized Glycosidase In the Absence of Stabilizers

Reduced and Non-Reduced, 10%

25 kGy 30 kGy 10 kGy 0 kGy 10 kGy

Gamma Irradiation of a Lyophilized Glycosidase In the Presence of 200mM Ascorbate



86h

Gamma Irradiation of a Lyophilized Glycosidase In the Presence of 200mM Ascorbate and 200mM Gly-Gly

Reduced & Non-Reduced, 10%

10 kGy

20 kGy

20 kGy

20 kGy

10 kGy

10 kGy

10 kGy

0 kGy